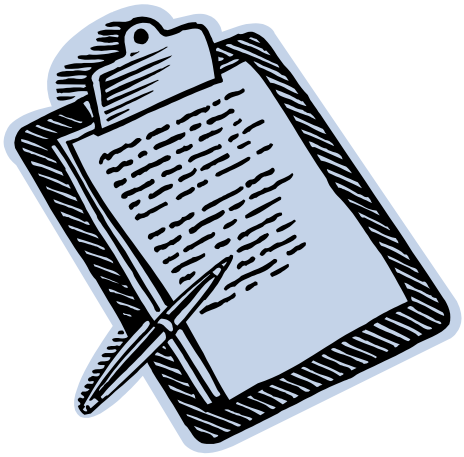
Validation and Verification of **HACCP** Plans in Retail Food Establishments

(Food Service and Retail Food Stores)

A Course for Retail Food Regulators

Learner Guide



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Massachusetts Department of Public Health

Revised August 2003

Validation and Verification of HACCP Plans In Retail Food Establishments

A publication of the Massachusetts Department of Public Health
Division of Food and Drugs - Food Protection Program.

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Revised August 2003

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Acknowledgements

The Department would like to acknowledge that this training curriculum and accompanying material was made possible by an FDA Innovative Food Safety Grant awarded to the Massachusetts Department of Public Health.

We would like to thank the following individuals who served as contributors and reviewers in the development and completion of these materials.

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Preface

During the past decade, retail food establishments have expanded their operations to include specialized food processing-type operations, such as smoking and curing, acidification, and reduced oxygen packaging, often using sophisticated new technologies and equipment. Such operations present a significant health risk if not conducted under strict operational procedures.

The Food and Drug Administration's (FDA) 1999 Food Code specifies that a HACCP plan, acceptable to the Regulatory Authority, be the basis for granting a variance for these specialized food processing operations. In addition, a HACCP plan or a food safety management plan based on HACCP principles may be required by the regulatory authority as part of a variance request for other food preparation or processing methods as they deem necessary.

For jurisdictions that have adopted the 1999 Food Code and/or additional requirements, regulators are responsible for ensuring that HACCP plans and plans based on HACCP principles (i.e. *Time as a Public Health Control* and *Preventing Contamination from Hands*) are effectively implemented to eliminate or significantly reduce targeted hazards that may contribute to foodborne illness. Regulators are responsible for ensuring that such plans as written are valid, in addition to verifying their effective implementation in the field.

In order to assist retail food regulators in fulfilling these responsibilities, the Massachusetts Department of Public Health Division of Food and Drugs received an FDA Innovative Food Safety Grant to develop HACCP training for regulators. This training has been designed to provide background information, public health rationale, regulations, and guidelines and controls for initiating, evaluating and verifying mandatory HACCP plans in retail food protection programs. Reference materials that will help facilitate the review and approval of HACCP plans were also developed and have been included.

Instructional materials in this training program are based on the *FDA's 1999 Food Code*, *FDA's Recommended National Food Regulatory Program Standards, FDA's Managing Food Safety: A HACCP Principles Guide for Operators of Food Establishments at the Retail Level and FDA Procedures for Standardization and Certification of Retail Food Inspection /Training Officers.*

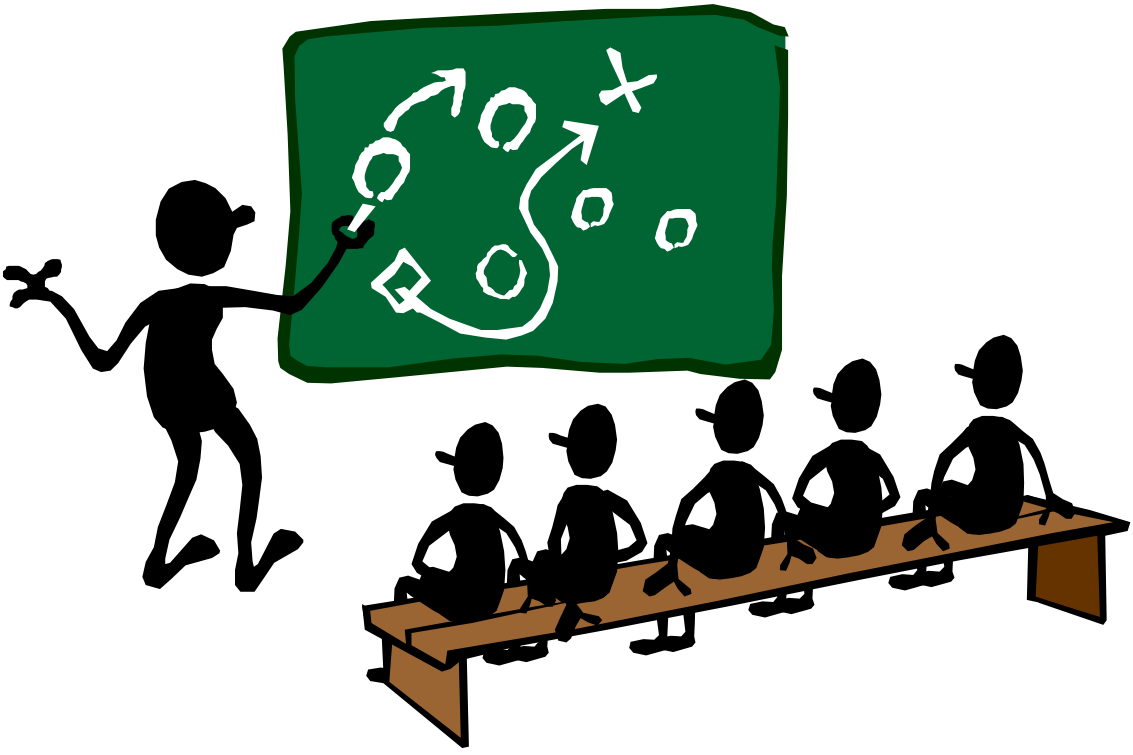
Note: *All information in this manual should be considered in light of new, or revised information available after publication. In addition, since this curriculum is primarily based on the 1999 Food Code, instructors/facilitators should customize the training to include state-specific requirements.*

Course Objectives

The instructional goal for learners is to be able to initiate, evaluate and verify mandatory HACCP and plans in retail food protection programs using the 1999 *Food Code*, *FDA's Recommended National Food Regulatory Program Standards, FDA's Managing Food Safety: A HACCP Principles Guide for Operators of Food Establishments at the Retail Level and FDA Procedures for Standardization and Certification of Retail Food Inspection / Training Officers.*

What will you learn during this workshop?

- Retail food processes that requires either a HACCP plan or a food safety management plan based on HACCP principles.
- Prerequisites for food safety systems based on HACCP principles
- Essential elements of a HACCP plan
- Significant hazards and preventive measures associated with specialized and high-risk food processes
- How to validate written plans submitted to a regulatory authority
- How to verify the effective implementation of HACCP plans that have been validated by a regulatory authority

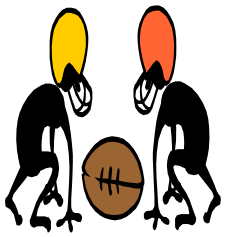


Module 1 REGULATORY APPLICATION OF HACCP IN RETAIL FOOD ESTABLISHMENTS

Objectives

After this session, you will be able to:

1. Identify processes and procedures that require a HACCP plan or a food safety management plan based on HACCP principles.
2. Identify and explain how the administrative provisions in the Food Code address variance requests, contents of a HACCP plan and conformance with approved procedures for mandated HACCP plans.



KEY TERMS

Active Managerial Control
The implementation and supervision of food safety practices to control risk factors by the person-in-charge.

Variance
A written document, issued by the regulatory authority, that authorizes a modification or waiver of one or more requirements of the Food Code if, in the opinion of the regulatory authority, it will not result in a health hazard or nuisance.

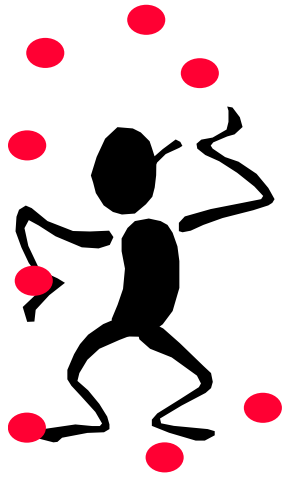
Regulator's Role and Responsibilities

The 1999 *Food Code*, recently adopted by Massachusetts, specifies that specialized food processing operations conducted at retail food establishments (i.e. reduced oxygen packaging, curing and smoking and acidification) are required to develop and implement a HACCP plan for that part of the operation.

These specialized processes have historically resulted in more foodborne illnesses than standard processes and, therefore, present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person-in-charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed process is carried out safely.

Regulators in jurisdictions that have adopted the 1999 Food Code or have additional requirements for mandatory food safety plans for the following processes and operations are responsible for ensuring that these plans are effectively implemented to eliminate or significantly reduce targeted hazards. Regulators are responsible for conducting a "regulatory" validation to ensure that the plan as designed is effective. In addition, the regulatory agency must also verify the effective implementation of the plan in the field. For the purpose of training, all plans will be referred to in this guide as HACCP plans. HACCP plans are mandatory for the following processes and operations:

1. Use of food additives or adding components such as vinegar as a method of food preservation or to render a food so that it is not potentially hazardous
2. Use of unpasteurized shell eggs in highly susceptible population (HSP) operations to prepare food in quantities other than single service portions
3. Reduced oxygen packaging (ROP) with barriers
4. Custom processing animals
5. Molluscan shellfish tanks
6. Smoking for preservation
7. Curing
8. Time as a public health control
9. Preventing contamination from hands



Each health department responsible for validating and verifying HACCP plans should have the necessary infrastructure that is conducive to the implementation of HACCP systems including knowledgeable sanitarians and clear assessment and enforcement policies and procedures.

Regulators are vital in promoting and encouraging "active managerial control" by providing guidance as to when a HACCP plan is necessary and how it can be successfully implemented. The key to successful implementation of HACCP plans depends on collaborative efforts between regulators, food operators and other food safety professionals.

The following regulations are taken directly from the 1999 Food Code and relate specifically to requirements for conducting specialized food processing operations at retail food establishments.

Regulation: 3-502.11 Variance Requirement

A food establishment shall obtain a variance from the regulatory authority as specified in § 8-103 before:

(1) Using food additives or adding components such as vinegar:

(a) As a method of food preservation rather than as a method of flavor enhancement
(b) To render a food so that it is not potentially hazardous

(2) Packaging food using a reduced oxygen packaging method except as specified under § 3-502.12 where a barrier to *Clostridium botulinum* in addition to refrigeration exists

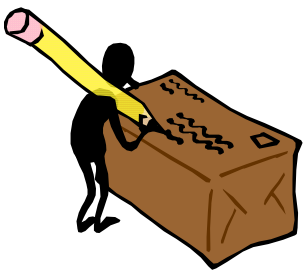
(3) Custom processing animals that are for personal use as food and not for sale or service in a food establishment

(4) Operating a molluscan shellfish life-support system display tank used to store and display shellfish that are offered for human consumption

(5) Smoking food as a method of food preservation rather than as a method of flavor enhancement

(6) Curing food

(7) Preparing food by another method that is determined by the regulatory authority to require a variance.



Regulation: 8-103.10 Modifications and Waivers

Regulatory authority may grant a variance by modifying or waiving the requirements of this Code if in the opinion of the regulatory authority – a health hazard or nuisance will not result from the variance. If a variance is granted, the regulatory authority shall retain the information specified under § 8-103.11 in its records for the food establishment.

Regulation: 8-103.11
Documentation of Proposed Variance and Justification

Before a variance from a requirement of this Code is approved, the information that shall be provided by the person requesting the variance and retained in the regulatory authority's file on food establishment includes:

(A) A statement of the proposed variance of the Code requirement citing relevant Code section numbers;

(B) An analysis of the rationale for how the potential public health Hazards and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and

(C) A HACCP plan if required as specified under § 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the variance requested.

NOTES:

Regulation: 8-201.13 When a HACCP Plan is Required

(A) Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as specified under § 8-201.14 and the relevant provisions of this Code if:

(1) Submission of a HACCP plan is required according to law;
(2) A variance is required as specified under § 3-502.11, ¶ 4-204.110(B), *or* Subparagraph 3-401.11(D)(3); *or*
(3) The regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal specified under § 8-201.12, an inspectional finding, or a variance request.

(B) A permit applicant or permit holder shall have a properly prepared HACCP plan as specified under § 3-502.12.

Regulation: 8-201.14 Contents of a HACCP Plan

For a food establishment that is required under § 8-201.13 to have a HACCP plan, the plan and specifications shall indicate:

(A) A categorization of the types of potentially hazardous foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority;

(B) A flow diagram by specific food or category type identifying critical control points and providing information on the following:

(1) Ingredients, materials, and equipment used in the preparation of that food, and

(2) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;

(C) Food employee supervisory training plan that addresses the food safety issues of concern;

Continued on next page…

(D) A statement of standard operating procedures for the plan under consideration including clearly identifying:

(1) Each Critical Control Point (CCP),
(2) The Critical Limits for each CCP,
(3) The method and frequency for monitoring and controlling each CCP by the food employee designated by the person-in-charge (PIC),
(4) The method and frequency for the PIC to routinely verify that the food employee is following standard operating procedures and monitoring CCPs,
(5) Action to be taken by the PIC if the critical limits for each CCP are not met, and
(6) Records to be maintained by the PIC to demonstrate that the HACCP plan is properly operated and managed; and

(E) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that FOOD safety is not compromised by the proposal.

Regulation: 8-103.12 Conformance with Approved Procedures

If the regulatory authority grants a variance as specified in § 8-103.10, or a HACCP plan is otherwise required as specified under § 8-201.13, the permit holder shall:

(A) Comply with the HACCP plans and procedures that are submitted as specified under § 8-201.14 and approved as a basis for the modification or waiver; and

(B) Maintain and provide to the regulatory authority, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring critical control points,
(2) Monitoring of the critical control points,
(3) Verification of the effectiveness of an operation or process, and
(4) Necessary corrective actions if there is failure at a critical control point

Module 2 HACCP REVIEW

Objectives

After this session, you will be able to:

1. Define HACCP and explain the HACCP Principles.
2. Provide examples of pre-requisite programs necessary for the effective implementation of HACCP plans.

Key Terms

a_w
A measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature

Control Point
Any point in a specific food system at which loss of control does not lead to an unacceptable health risk.

Critical Control Point
A point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

Critical Limit
The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize risk that the identified food safety hazard may occur.

Deviation
Failure to meet a required critical limit for a critical control point.

Good Retail Practices (GRPs)
Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the Food Code interventions or risk factors.

HACCP
An acronym for Hazard Analysis Critical Control Point

Hazard Analysis Critical Control Point (HACCP)
A prevention-based food safety system that identifies and monitors specific food safety hazards that can adversely affect the safety of food products.

HACCP Plan
A written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee for the Microbiological Criteria for Foods.

HACCP System
The result of implementing the HACCP principles in an operation that has foundational comprehensive, prerequisite programs in place. A HACCP system includes the HACCP plan and all prerequisite programs.

Hazard
A biological, chemical, or physical property that may cause an unacceptable consumer health risk.

Hazard Analysis
The process of collecting and evaluating information about hazards associated with the food under considerationto decide which are significant and must be addressed in the HACCP plan.

Monitoring
A planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an interrupted record of data.

pH
The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution***.***

Potentially Hazardous Food
A food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms; the growth and toxin production of *Clostridium botulinum*, or in raw shell eggs, the growth of *Salmonella* Enteritidis.

Prerequisites for HACCP
Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety, as described in Codex Alimentarius Commission's Principles of Food Hygiene and other Codes of Practice.

Preventive Measure
An action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.

Risk
The likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

Risk Factor
One of the factors identified by the Centers for Disease Control and Prevention (CDC) as a contributor to the foodborne outbreaks that have been investigated and confirmed. The factors are unsafe sources, inadequate cooking, improper holding, contaminated equipment and poor personal hygiene.

Severity
The seriousness of the effect(s) of a hazard.

Standard Operating Procedure (SOP)
A detailed set of instructions, steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable to the production of safe food. These written procedures are often equivalent to prerequisite programs of HACCP. The extent to which operators employ various SOPs will determine which critical control points need to be controlled.

Validation
Validation is that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Verification
Verification means those activities other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

HACCP Overview

Simply stated, Hazard Analysis Critical Control Point (HACCP) is a logical and thorough process control system designed to identify and control hazards. HACCP focuses on prevention and control of food safety problems at highly specific (and controllable) points in the process chain. Implementing a well-designed HACCP program provides food manufacturers and food handlers a high level of control over product safety.

HACCP has been around since the 1960's, when the Pillsbury Company introduced it in the production of foods for the space program. The application of HACCP is based on sound technical and scientific principles that assure food safety. Recently, numerous meat and poultry operations have been mandated to utilize HACCP to address concerns with food safety.

HACCP plans should be specific for each operation. Committed personnel involved in the processing operation should conduct the design and implementation of a HACCP plan.

Although many of the larger food establishments and chains have the expertise available to develop and implement HACCP systems, some of the smaller establishments may require assistance from university extension programs, industry associations, consultants, and government for development of their plans.

Prerequisite Programs

HACCP is not a stand-alone program. HACCP systems must be built upon a firm foundation of compliance with current Good Retail Practices (GRPs) and Standard Operating Procedures (SOPs). GRPs and SOPs affect the retail environment and should be considered prerequisite programs to HACCP. GRPs cover areas of general hygiene as well as controls that prevent food from becoming contaminated due to unsanitary conditions.

SOPs are procedures used to accomplish the overall goal of maintaining GRPs. They describe a particular set of objectives associated with sanitary handling of food and the cleanliness of the retail environment.

For example, SOPs can help control bacterial hazards by specifying procedures to:

1. Avoid product cross-contamination by proper product flow and limiting employee tasks and movement
2. Locate hand washing and sanitizing stations near the food preparation area to facilitate proper hand washing
3. Ensure appropriate equipment maintenance and cleaning/sanitizing procedures

When GRPs and SOPs are in place, HACCP can be more effective because it can concentrate on the hazards associated with the food or preparation and *not* on the retail environment or maintenance of facilities.

Example of programs that are valuable in supporting the HACCP system include:

- Personal hygiene
- Preventive maintenance plans
- Pest control
- Equipment and operation design
- Employee training
- Product identification and coding

HACCP Principles

In November 1992, the National Advisory Committee on Microbiological Criteria for Food (NACMCF) defined seven widely accepted HACCP principles that were to be considered when developing a HACCP plan. In 1997, the NACMCF reconvened the HACCP Working

Group to review the Committee's November 1992 HACCP document and to compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene.

From this committee, HACCP was defined as a systematic approach to the identification, evaluation and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.
Principle 2: Determine the critical control points (CCPs).
Principle 3: Establish critical limits.
Principle 4: Establish monitoring procedures.
Principle 5: Establish corrective actions.
Principle 6: Establish verification procedures.
Principle 7: Establish record-keeping and documentation procedures.

Principle 1: Conduct a Hazard Analysis

A ***food hazard*** is any unacceptable contamination by a biological, chemical, or physical agent at sufficient level to cause a food to be unsafe for human consumption. By far the most common agents are biological, mainly pathogenic bacteria, other microorganisms and parasites.

Biological hazards include: bacteria, bacterial toxins, viruses and parasitic organisms that could survive, grow, or contaminate food products/raw materials, and potentially cause foodborne illness. (See chart entitled: *Selected Factors Influencing Growth of Common Foodborne Pathogens* following Principle #7.)

Chemical hazards could result from a number of sources: agricultural chemicals, insecticides, fungicides, etc.; cleaning/sanitizing agents and chemicals, certain naturally-occurring toxins such as Scombrotoxin (histamine), Ciguatoxin, mycotoxins from mold, shellfish toxins, etc. and misuse of food chemicals (preservatives, additives, etc.).

Physical hazards include: inadvertent field matter (stones, wood, metal fragments, etc.); inadvertent processing residues (glass, metal fragments, etc.); intentional materials (employee sabotage) and miscellaneous particulates and fragments.

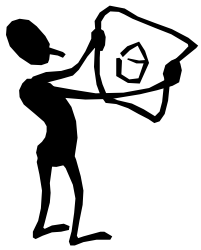
The HACCP team should evaluate hazards of significance and preventative measures needed for each food product and process. They should use as many sources of information as possible in this evaluation phase: scientific literature, opinions of experts, laboratory records, and specifications.

Principle 2: Identify Critical Control Points

A ***Critical Control Point (CCP)*** means a point or procedure, in a specific food system, where loss of control may result in an unacceptable health risk.

CCPs are not limited to those processes or operations which eliminate hazards. CCPs can also be identified where hazard prevention or reduction can occur (e.g., ingredient or raw material specifications, sanitation programs, etc.).

Identification of CCPs is an important and painstaking process and provides the backbone of HACCP. In addition to the element of hazard control at a CCP, it is equally important that such control can be monitored and adequately verified (see Principles 4 and 7).



Thoroughly discuss the selection of CCPs. Once identified, CCPs should be clearly labeled on product flow chart(s).

Principle 3: Establish Critical Limits

A ***Critical Limit (CL)*** is a safe limit or tolerance that must be met for each identified CCP. These are the boundaries of safety for the microbiological, chemical and physical hazards. Exceeding these boundaries indicates that a health hazard may exist or could develop.

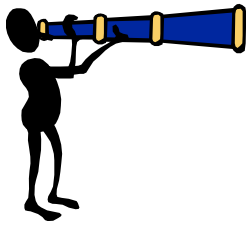
The most obvious examples of such limits are specific temperature/time relationships for either processing or storage that are necessary to prevent, eliminate or reduce microbial hazards. Food composition information such as acidity may also be used.

Other examples of critical limits include: specifications on raw materials/ingredients (e.g., an ingredient shall be free of *Salmonella,* or parasites).

Care must be exercised; critical limits must be identified for each CCP and these critical limits must be realistic and be *measurable*.

Principle 4: Establish Monitoring/Inspection Requirements

Monitoring is a scheduled observation or measurement of a CCP and its limits. The purpose of monitoring is two-fold: to assess whether a CCP is under control and to generate data that will be used to produce an accurate record for future verification. Monitoring procedures should be accurate and done at appropriately established frequency.



Visual observations are usually based upon a predetermined inspection checklist, which usually involves observing temperatures, or cleanliness of equipment. Chemical testing may include measuring pH or acidity, or sanitizer levels Sensory monitoring involves examining raw materials for "off" odors, presence of molds, or other defects.

Microbiological testing has a limited but important role due to the time delay involved for results. While it is not possible to use microbial data to stop a process on the spot or to bring a CCP under control, microbial testing is used to set/maintain acceptance

standards on raw materials and ingredients in hazard analysis. Microbial data may also be used in HACCP verification (see Principle 7).

Principle 5: Establish Corrective Actions

A ***Corrective Action*** is a procedure followed when a deviation occurs. Corrective actions must be taken whenever monitoring indicates that limits or tolerances are not met. Such action must be immediate to assure that the situation is rectified. Action will vary with the process being monitored and the type of monitoring indicated. Based upon the severity of hazard and the individually defined situation, corrective action may involve: notifying a supervisor, process line shut down, reprocessing, adjusting process temperature and times, rejecting raw materials or ingredients, and holding or recalling product in distribution. Corrective actions must be identified and documented in the HACCP plan and should specifically address each CCP. It is fundamentally important to specifically delineate responsibility and authority with regard to corrective action.

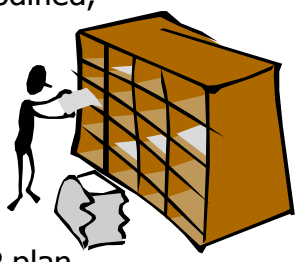
Principle 6: Establish Verification Procedures

A working HACCP system is dynamic and flexible, and allows for change. It should have provisions for verification of its effectiveness.

Verification is a process designed to:

- Review the HACCP plan
- Establish whether the CCPs and CLs are being adequately controlled and monitored
- Determine if the procedures for product deviations and record keeping are being followed correctly

Verification involves actual observation of procedures and a thorough review of records. The verification team should be clearly identified and empowered. On-going verification should be on a well-defined and established frequency, i.e. once per shift, daily, weekly, etc. However, a comprehensive HACCP system verification should be conducted at least annually or whenever there is a change in the HACCP system. If the results of that comprehensive verification identify deficiencies, the HACCP plan must be modified, as necessary, to ensure the HACCP plan is controlling the hazards.



Principle 7: Establish a Record Keeping System

An ***adequate record keeping system*** is the heart of a HACCP program.

Records are the documentation needed to verify effectiveness of the HACCP plan. They are the only reference available to trace the production history of a finished product. If questions arise concerning the product, a review of the records may be the

only way to ascertain or prove that the product was prepared and handled in a safe manner in accordance with all the HACCP principles outlined in the establishment's HACCP plan.

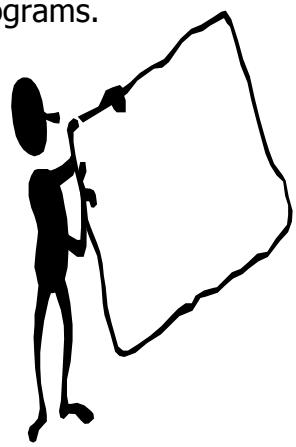
Adherence to the specific critical limits (CLs) set at each CCP is the best assurance of product safety. Documenting the data from those measurements results in a permanent record. Records provide a dual function by providing a history of performance, as well as any actions taken to prevent a problem.

In order to assure product safety and to document processes and procedures, HACCP records must contain the following information:

- Title and date of record
- Product identification
- Materials and equipment used
- Operations performed
- Critical criteria and limits
- Corrective action to be taken and by whom
- Operator identification
- Monitoring data
- Reviewer's initials and date of review

HACCP System

A complete HACCP system is the result of implementing the HACCP principles in an operation that has a solid foundation of comprehensive, prerequisite programs in place. A HACCP system includes the HACCP plan and all prerequisite programs.



Selected Factors Influencing Growth of Common Foodborne Pathogens

Pathogen	Min. a_w	Min. pH	Max. pH	Max. % salt	Min. temp.	Max. temp.	Oxygen Requirement
Bacillus Cereus	.92	4.3	9.3	18	39.2°F 4°C	131°F 55°C	aerobe
Campylobacter jejuni	.987	4.9	9.5	1.5	86°F 30°C	113°F 45°C	micro-aerophilic*
Clostridium botulinum, type A, and proteolytic B and F	.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe**
Clostridium botulinum, type E, and nonproteolytic B and F	.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe**
Clostridium perfringens	.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe**
Escherichia coli Pathogenic strains	.95	4	9	6.5	44.6°F 7.0°C	120.9°F 49.4°C	facultative anaerobe***
Listeria monocytogenes	.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe***
Salmonella spp.	.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe***
Shigella spp.	.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe***
Staphylococcus aureus-growth	.83	4	10	25	44.6°F 7°C	122°F 50°C	facultative anaerobe***
Staphylococcus aureus-toxin	.85	4	9.8	10	50°F 10°C	118°F 48°C	facultative anaerobe***
Vibrio cholerae	.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe***
Vibrio parahaemolyticus	.94	4.8	11	10	41°F 5°C	111°F 44°C	facultative anaerobe***
Vibrio vulnificus	.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe***
Yersinia enterocolitica	.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe***

*requires limited levels of oxygen ** requires the absence of oxygen ***grows with or without oxygen

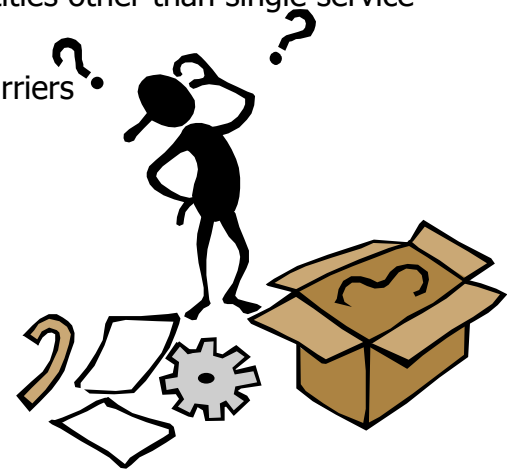
Fish and Fisheries Products Hazards and Controls Guidance: *Third Edition*

Module 3 SPECIALIZED PROCESSES AND PROCEDURES REQUIRING A HACCP PLAN

Objective

After this session, you will be able to identify preventive measures commonly used for controlling hazards associated with specialized processing methods and high risk procedures including:

- Use of food additives or adding components such as vinegar as a method of food preservation or to render a food so that it is not potentially hazardous
- Use of unpasteurized whole shell eggs in highly susceptible population (HSP) operations to prepare food in quantities other than single service portions
- Reduced oxygen packaging (ROP) with barriers
- Custom processing animals
- Molluscan shellfish tanks
- Smoking for preservation
- Curing
- Time as a public health control
- Preventing contamination from hands



Key Terms

Highly Susceptible Population
Persons who are more likely than other people in the general population to experience foodborne disease because they are:

a) Immunocompromised; preschool age children, or older adults; and
b) Obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

Molluscan Shellfish
Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, *except when the scallop product consists only of the shucked adductor muscle*.

Acidification/Adding Components to Render Food Non-Potentially Hazardous

Public Health Rationale

A Hazard Analysis Critical Control Point (HACCP) plan is necessary when conducting specific food processes such as acidification. Such processes have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. The HACCP plan must be maintained at the retail site for review by the regulatory authority.

Cooked rice is a potentially hazardous food (phf). If the pH of the rice is not brought down below 4.6, it may be able to support the growth of pathogens when stored at room temperature. The preparation of acidified (adding vinegar) sushi rice may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

Regulation: 3-502-11 Specialized Processes

Any food establishment, which acidifies rice in order to render it a non-potentially hazardous food, must obtain a variance from the board of health (BOH) in accordance with FC 3-502.11 Variance Requirement. A request for such a variance must be accompanied by a HACCP plan in accordance with FC 8-201.13.
FC 8-201.14 identifies the required contents of a HACCP plan including the identification of hazards, critical control points (CCPs), monitoring procedures, critical limits and corrective actions. The plan must also identify records maintained for monitoring CCPs and methods for verifying that the plan is working.

Controls and Guidelines

Example: Making sushi rice

The HACCP plan must include the following:

1. There must be a written recipe or formulation for acidifying the rice.
   - The recipe must contain the weights of rice and water needed prior to cooking.
   - The recipe must be validated by a food laboratory to show that it results in cooked rice that has a target pH of 4.1.
   - Any change in the recipe would require lab validation of the new recipe before it may be used. (For example, switching to a new brand of vinegar is a significant change and necessitates the revalidation of the recipe.)

2. Cooked rice must be cooled in a shallow container that is less than 4" deep to promote rapid cooling of product and uniform acidification.

3. One of the CCPs must be the pH of the cooked rice.

4. A calibrated pH meter or pH test strips must be used, according to manufacturer's instructions, to monitor the pH of every batch of acidified rice.

5. The pH strips must be able to detect 0.1 unit differences in pH. The target pH should be 4.1 but must not exceed 4.6.

6. The results of the pH measurement of each batch of rice must be properly recorded, and the records must be retained for 30 days.

Guideline For Validating Acidified Rice HACCP Plans

Prerequisites and Standard Operating Procedure(s) (SOPs)
- ❑ Most recent inspection reports indicate compliance with all regulations. Any pre-existing violations, which may result in biological, physical or chemical contamination of this product, have been corrected.
- ❑ Manufacturer specifications and calibration instructions for pH meter or pH paper used/provided (.1 scale)
- ❑ 4.01 or 7.0 buffer solution used (based on manufacturer's recommendations)
- ❑ Instruction for measuring pH of rice slurry provided
- ❑ Distilled water provided for making rice slurry (when required by pH testing instructions)

Recipe/Formulation Provided
- ❑ Brand(s)/concentration of vinegar identified
- ❑ Preparation steps identified

Hazard Analysis Included
- ❑ Growth of *B.cereus and* production of toxins identified

CCP Identified
- ❑ Acidifying step (addition of vinegar to rice)

Critical Limit Identified
- ❑ pH of acidified rice not to exceed 4.6

Monitoring Procedures Identified
- ❑ Calibrated pH meter or pH papers used to measure each batch of acidified rice
- ❑ Person(s) identified for testing pH of rice

Corrective Actions and Documentation Procedures Identified

If rice has not been tested with the pH meter, do not use until it is tested.

<u>If pH of rice is noted above 4.6:</u>
- ❑ Discard rice if **not** made within the hour
- ❑ If rice was made within the hour, add additional vinegar and re-test pH
- ❑ Verify use of correct recipe and procedures
- ❑ Verify calibration and proper use of pH meter or pH test papers

Verification Process Identified (Short Term/Long Term)
- ❑ pH meter calibrated daily when used
- ❑ Monitoring records reviewed, on a weekly basis, or as needed, by PIC
- ❑ Recipe/formulation (</= pH 4.1) validated, signed and dated by a food laboratory
  - when recipe is modified, *or*
  - when daily pH levels are consistently higher than the laboratory validated pH measurement
- ❑ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

Records are Identified
- ❑ pH log for each batch of rice (sample page included) maintained for 30 days
- ❑ Daily calibration log maintained for pH meter
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Laboratory test results, conducted annually, maintained for one year

Employee Training Plan Documented (sample of training log provided)
- ❑ Employee Health and Hygiene
- ❑ Cleaning and Sanitizing Procedures
- ❑ Cross-contamination Prevention Procedures
- ❑ Monitoring Procedures for Acidified Rice
- ❑ Use of pH meter or pH papers
- ❑ Corrective Actions
- ❑ Recordkeeping Requirements

Pasteurized Foods and Prohibited Food – Whole Shell Eggs

Public Health Rationale

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multi-state outbreak of *Salmonella* Enteritidis traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

The food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to *Salmonella* Enteritidis.

Regulation: 3-801.11 Pasteurized Foods and Prohibited Food

In a food establishment that serves a highly susceptible population:

The following criteria apply to eggs that are used in HSP operations to prepare potentially hazardous foods in quantities other than single service portions.

(B) Pasteurized shell eggs or pasteurized liquid, frozen, or dry eggs or egg products shall be substituted for raw shell eggs in the preparation of:

(1) Foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and egg-fortified beverages, and

(2) Except as specified in ¶ (E) of this section, recipes in which more than one egg is broken and the eggs are combined;

(E) *Subparagraph (B)(2) of this section does not apply if:*

(1) The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled eggs;

(2) The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread; or

Continued on next page…

Controls and Guidelines

(3) The preparation of the food is conducted under a HACCP plan that:

(a) Identifies the food to be prepared,
(b) Prohibits contacting ready-to-eat foods with bare hands,
(c) Includes specifications and practices that ensure:

(i) *Salmonella* Enteritidis growth is controlled before and after cooking, and
(ii) *Salmonella* Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in subparagraph 3-401.11(A)(2),

(d) Contains the information specified under § 8-201.14(D) including procedures that:

(i) Control cross contamination of ready-to-eat food with raw eggs, and
(ii) Delineate cleaning and sanitization procedures for food contact surfaces, and

(e) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

Guideline For Validating Whole Shell Eggs For HSP HACCP Plans

Prerequisites and Standard Operating Procedure(s) (SOPs)

- ❑ Most recent inspection reports indicate compliance with all regulations. Pre-existing violations, which may result in biological/physical/chemical contamination of product, have been corrected.
- ❑ Instructions provided for combining raw eggs immediately before cooking
- ❑ Guidelines provided that prohibit cross-contamination of ready-to-eat food with raw eggs / bare hands
- ❑ Cleaning and sanitizing procedures for food contact surfaces delineated

Recipe/Formulation Provided

- ❑ Pooling Eggs - Preparation steps identified

Hazard Analysis Included

- ❑ Pathogen survival – *Salmonella* Enteriditis

CCP Identified

- ❑ Cooking

Critical Limit Identified

- ❑ Internal final product temperature of 155°F

Monitoring Procedures Identified

- ❑ Calibrated thermometer used to measure final internal product temperature
- ❑ Person(s) identified for measuring temperature of final product

Corrective Actions and Documentation Procedures Identified

- ❑ Process extended, or temperature elevated until proper internal temperature is reached
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Cause of deviation determined

Verification Process Identified (Short Term/Long Term)

- ❑ Thermometer calibrated weekly, or as needed, by PIC
- ❑ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC
- ❑ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

Records are Identified

- ❑ Cook log for each product (sample page included)
- ❑ Daily calibration log maintained for thermometer
- ❑ Corrective action record

Employee Training Plan Documented (sample of training log provided)

- ❑ Employee Health and Hygiene
- ❑ Cleaning and Sanitizing Procedures
- ❑ Cross-contamination Prevention Procedures
- ❑ Monitoring Procedures
- ❑ Calibration of Thermometer(s)
- ❑ Corrective Actions
- ❑ Recordkeeping Requirements

Reduced Oxygen Packaging (ROP)

Key Terms

Reduced Oxygen Packaging is defined as any packaging procedure that results in a reduced oxygen level in a sealed package. The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding, 21% oxygen atmosphere, and a ROP process that involves a food for which Clostridium botulinum is identified as a microbiological hazard in the final packaged form. The term is often used because it is an inclusive term and can include other packaging options such as:

Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a plastic or metal crimp.

Controlled Atmosphere Packaging (CAP) is an active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. Controlled Atmosphere Packaging (CAP) is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.

Modified Atmosphere Packaging (MAP) is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. Modified Atmosphere Packaging (MAP) is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, 0.03% carbon dioxide.

Sous Vide is a specialized process of ROP for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization step that reduces bacterial load but is not sufficient to make the food shelf-stable. The process involves the following steps:

(a) Preparation of the raw materials (this step may include partial cooking of some or all ingredients);

(b) Packaging of the product, application of vacuum, and sealing of the package;

(c) Pasteurization of the product for a specified and monitored time/temperature;

(d) Rapid and monitored cooling of the product at or below (38°F) or frozen; and

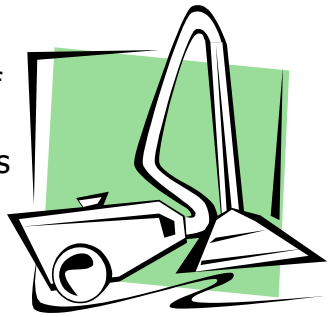
(e) Reheating of the packages to a specified temperature before opening and service.

Vacuum Packaging reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.

Public Health Rationale

Use of reduced oxygen packaging (ROP), with some foods, provides the potential for growth of several important pathogens, thereby markedly increasing safety concerns.

An anaerobic environment, usually created by ROP, prevents the growth of aerobic spoilage organisms. These aerobic organisms are responsible for off-odors, slime, and texture changes, which are signs of spoilage. The inhibition of these spoilage organisms is significant because, without them, tell-tale signs signaling that the product is no longer fit for consumption will not occur.



ROP processors and regulators must assume that during distribution of foods, or while being held by retailers or consumers, refrigerated temperatures may not be consistently maintained. A serious concern is that the increased use of vacuum packaging at retail and supermarket deli-type operations may be followed by temperature abuse in the establishment or by the consumer.

If products in ROP are subjected to mild temperature abuse, i.e., 41°-53°F, at any stage during storage or distribution, foodborne pathogens, including *Bacillus cereus*, *Salmonella* spp., *Staphylococcus aureus*, and *Vibrio parahaemolyticus* can grow slowly. Also, marginal refrigeration, that does not facilitate growth, may still allow *Salmonella* spp., *Campylobacter* spp., and *Brucella* spp. to survive for long periods of time.

Consequently, one or more growth barriers must be used with refrigeration to control pathogenic outgrowth. Growth barriers are provided by hurdles such as low pH, a_w, or short shelf life, and constant monitoring of the temperature.

Processed products such as meat and cheese, which have undergone an adequate cooking step to kill *L. monocytogenes,* can be contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place. Relying on refrigeration as the sole barrier to product safety requires very rigorous temperature controls and monitored refrigeration equipment.

In addition, refrigerated foods packaged at retail may be chilled either after they are physically prepared and repackaged, or packaged after a cooking step. In these situations, it is important to inhibit the germination of *Clostridium botulinum* spores because spores are not destroyed by a heating step.

If extended shelf life is sought, a temperature of 38°F or lower must be maintained at all times to prevent outgrowth of *C. botulinum* and the subsequent production of toxin. If a retail establishment wishes to use an ROP process, microbiological studies should be performed by, or in conjunction with, an appropriate process authority, or person knowledgeable in food microbiology, who is acceptable to the regulatory authority.

Regulation: 3-502.12 Reduced Oxygen Packaging (ROP)

(A) Except for a food establishment that obtains a variance as specified under § 3-502.11, a food establishment that packages food using a ROP method and *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form shall ensure that there are at least two barriers in place to control the growth and toxin formation of *C. botulinum*.

(B) A food establishment that packages food using a ROP method and *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form shall have a HACCP plan that contains the information specified under ¶ 8-201.14(D) and that:

(1) Identifies the food to be packaged
(2) Limits the food packaged to a food that does not support the growth of *Clostridium botulinum* because it complies with one of the following:

(a) Has an a_w of 0.91 or less,
(b) Has a PH of 4.6 or less,
(c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 318.7: Approval of substances for use in the preparation of products and 9 CFR 381.147: Restrictions on the use of substances in poultry products and is received in an intact package, or
(d) Is a food with a high level of competing organisms such as raw meat or raw poultry;

(3) Specifies methods for maintaining food at 5°C (41°F) or below;

(4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
(a) Maintain the food at 5°C (41°F) or below, and
(b) For food held at refrigeration temperatures, discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;

(5) Limits the refrigerated shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

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(6) Includes operational procedures that:
- (a) Prohibit contacting food with bare hands,
- (b) Identify a designated area and the method by which:
  - (i) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross-contamination
  - (ii) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, and
- c) Delineate cleaning and sanitization procedures for food contact surfaces and

(7) Describes the training program that ensures that the individual responsible for the ROP operation understands the:
- (a) Concepts required for a safe operation,
- (b) equipment and facilities, and
- (c) Procedures specified under Subparagraph (B)(6) of this section and ¶ 8-201.14(D).

(C) Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a ROP method.

Controls and Guidelines (Reduced Oxygen Packaging)

All food establishments packaging food in a ROP atmosphere must develop a HACCP plan and maintain the plan on-site for review by the regulatory authority. In addition, those foods being packaged using a ROP method, but do not have at least two safety barriers, also require a variance.

Some common foods, which require a variance under 3-502.11, include, but are not limited to, processed fish, smoked fish, caviar, soft cheeses such as ricotta, cottage cheese, cheese spreads, and combinations of cheese and other ingredients such as vegetables, meat, poultry or fish, meat or poultry products which are smoked or cured and raw food of animal origin which is cured in a USDA-regulated processing plant, or establishment approved by the regulatory authority to cure these foods may be smoked in accordance with approved time/temperature requirements and packaged in ROP at retail if approved by the regulatory authority.

Note: There may be some foods, such as dry pasta, noodles, or crackers that may not require either a HACCP plan or a variance because *Clostridium botulinum* has not been identified as a microbiological hazard in the final packaged form.

Safety Barrier Verification

The safety barriers for all processed foods held in ROP at retail must be verified in writing. This can be accomplished in two ways:

- Written certification from the product manufacturer
- Independent laboratory analysis using methodology approved by the regulatory

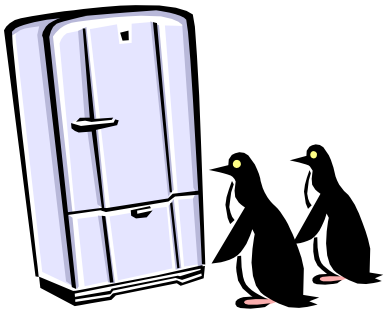
Note: The Association of Food and Drug Officials (AFDO) guidelines recommend that laboratory analysis be conducted by official methods of the Association of Official Analytical Chemists (AOAC).

Recommendations for ROP Without Multiple Barriers

Employee Training

If ROP is used, employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines and the potential hazards associated with these foods.

At the discretion of the regulatory authority, a description of the training and course content, provided to the employees, must either be available for review or have prior approval by the regulatory authority.



Refrigeration Requirements

Foods in ROP that have only one barrier, i.e., refrigeration, to *C. botulinum*, must be refrigerated to 41°F or below and marked with a use-by date within either the manufacturer's labeled use-by date or 14 days after preparation at retail, whichever comes first.

Any extension of shelf life past 14 days will require a further variance that considers lower refrigeration temperatures. Foods that are intended for refrigerated storage beyond 14 days must be maintained at or below 38°F.

Alternatively, foods packaged by ROP may be kept frozen if freezing is used as the declared primary safety barrier.

Labeling - Refrigeration Statements

All foods in ROP which rely on refrigeration as a barrier to microbial growth must bear the statement "Important - Must be kept refrigerated at 41°F" or "Important - Must be kept frozen," in the case of foods which rely on freezing as a primary safety barrier.

The statement must appear on the principal display panel in bold type on a contrasting background.

Foods held under ROP, which have lower refrigeration requirements as a condition of safe shelf life, must be monitored for temperature history and must not be offered for retail sale if the temperature and time specified in the variance are exceeded.

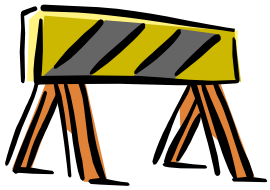
Labeling - "Use-by date"

- Each container of food in ROP must bear a "use-by" date.
- This date may not exceed 14 days from retail packaging or repackaging without a further variance granted by the regulatory authority.
- The date assigned by a re-packer may not extend beyond the manufacturer's recommended "pull date" for the food.
- The "use-by" date must be listed on the principal display panel in bold type on a contrasting background.
- Any label must contain a combination of a "sell-by" date and use-by instructions which makes it clear that the product must be consumed within 14 days of retail packaging or repackaging, as an acceptable alternative to a 14 day "use-by" date, i.e., for product packaged on November 1, 1999 - "Sell by November 10, 1999" - use within 4 days of sell-by date.
- Foods that are frozen, before or immediately after packaging, (and remain frozen until use) should bear a "Keep frozen, use within 4 days after thawing" statement.

Disposition of Expired Product at Retail

Processed reduced oxygen foods that exceed the "use-by" date or manufacturer's "pull date" cannot be sold in any form and must be disposed of in a proper manner.

Dedicated Area/Restricted Access



- All aspects of reduced oxygen packaging shall be conducted in an area specifically designated for this purpose.
- There shall be an effective separation to prevent cross contamination between raw and cooked foods.
- Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in food packaged by an ROP method.
- Some ROP procedures such as sous vide may require a "sanitary zone" or dedicated room with restricted access to prevent contamination.

The HACCP plan must also include a listing and proportion of food-grade gasses used and a standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

Guideline For Validating Reduced Oxygen Packaging HACCP Plans

(High Level of Competing Organisms)

Prerequisites and Standard Operating Procedure(s) (SOPs)

- ❑ Most recent inspection reports indicate compliance with all regulations. Pre-existing violations, which may result in biological/physical/chemical contamination of product, have been corrected.
- ❑ Guidelines that prohibit contacting food with bare hands provided
- ❑ Designated area/physical barriers/methods of separation of raw foods and ready-to-eat foods identified
- ❑ Access to processing equipment limited to responsible, trained personnel
- ❑ Cleaning and sanitizing procedures for food contact surfaces delineated

Hazard Analysis Included

- ❑ Pathogenic growth, particularly *Clostridium botulinum* spores

CCP Identified

- ❑ Labeling
- ❑ Storage

Critical Limit Identified

Labeling

- ❑ Packages prominently and conspicuously labeled with:
  - product name
  - date of packaging
  - "*use-by*" date
  - ingredient statement (where necessary)
- ❑ The *"Use By"* date does not exceed 14 days from the retail vacuum packaging date
- ❑ Date assigned by the retailer does not exceed the manufacturer's recommended *"Pull Date"*

Storage

- ❑ Maximum cooler temperature 41°F

Monitoring Procedures Identified

Labeling

- ❑ One finished product label from each batch visually inspected for appropriate "use-by" date and label statement .

Storage

- ❑ Cooler air temperature measured on a daily basis, or as needed, by PIC
- ❑ Person(s) identified for monitoring temperature of cooler daily

Corrective Actions and Documentation Procedures Identified

Labeling

- ❑ Improperly labeled product segregated and re-labeled
- ❑ Products not sold within the *"use-by"* date discarded
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Cause of deviation determined

Storage

- ❑ Products exceeding 41°F, held pending evaluation of time/temperature exposure
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Determine cause of deviation

Verification Process Identified (Short Term/Long Term)

Labeling and Storage

- ❑ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC
- ❑ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

Storage

- ❑ Thermometer calibrated monthly, or as needed

Records are Identified

Labeling

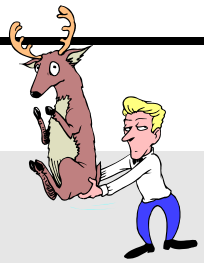
- ❑ Label check record

Storage

- ❑ Temperature logs
- ❑ Corrective action record

Employee Training Plan Documented (sample of training log provided)

- ❑ Employee Health and Hygiene
- ❑ Cleaning and Sanitizing Procedures
- ❑ Cross-contamination Prevention Procedures
- ❑ Monitoring Procedures Meeting Critical Limits
- ❑ Corrective Actions
- ❑ Recordkeeping Requirements



Custom Processing Animals

Key Terms

Custom Processing
Preparing/processing of animals who have died by means other than slaughtering and whose product is not to be sold or given away and is only for the use of the owner of the animal, his family and/or non-paying guests

Field dressed
Field dressed means that the body cavity has been opened and the internal organs removed.

Game Animals
An animal, the products of which are food, that is not classified as cattle, sheep, swine, goat, horse, mule, or other equine under USDA 9 CFR or as fish as defined in the Food Code.

Examples: mammals such as reindeer, elk, deer, antelope, buffalo, bison, llama, moose, ducks, rabbits, opossum, raccoon, squirrel, nutria, or muskrat and nonaquatic reptiles such as land snakes.

Public Health Rationale

The purpose of requiring a variance and a HACCP plan, when custom processing animals that are for personal use as food is to ensure that this process is conducted in a sanitary manner. It is also necessary to ensure that these animals, intended for private use, do not get into the food chain, as they are considered an unapproved food source.

The primary concern regarding this type of specialized process is that these animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness in humans. Some of these diseases can be severe in the human host.

It is imperative, to avoid cross-contamination, that these animals, which are not inspected under USDA, be processed separately from all other products for sale to the consumer. Strict adherence to proper hand washing techniques and cleaning and sanitizing procedures is also required to prevent microbiological contamination and prevent cross-contamination.

Although when discussing sanitation, the emphasis is placed on the environment, the products themselves must not be over-looked. Dirty or spoiled meat products entering a sanitary environment are not only unacceptable in themselves, but place the environment at risk as well.

Regulation: 3-502.11 Specialized Processes

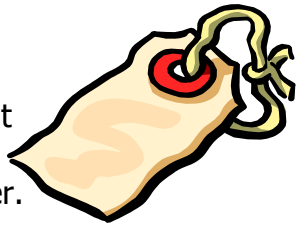
All domesticated meat and poultry **<u>whose product is intended for sale</u>** must be slaughtered and processed in a U. S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) inspected facility. The facility must be subject to mandatory or exempt inspection by USDA/FSIS. All USDA/FSIS inspected facilities are subject to licensure by the MA Department of Public Health (DPH).

Any food establishment intending to process either meat and poultry raised for private use, or "*field dressed*" game animals intended for private use, is required to apply for a variance and submit a HACCP plan.

Controls and Guidelines

The following guidelines are recommended to ensure that any custom processed animals stored in the establishment must be contained and handled so that there is complete separation from all other products for sale to the consumer.

1. Provide a written list of days and times when game animals are processed.



2. Attach a tag, with the words "NOT FOR SALE" in letters at 3/8" in height, to all incoming carcasses. Tags must also include a space for assigning a designated carcass number. (A label may also be stamped directly onto the carcass.)

3. Keep a record (log book) of the name and address of the owner of each carcass, the species, date received, dressed weight and the assigned designated carcass number to the tag. Records should be maintained for at 90 days and should be available, during reasonable hours, for inspection by regulators.

4. Any equipment used to process game animals or meat must be thoroughly cleaned and sanitized before it can be used for processing domestic meat, poultry, fish, ready-to-eat foods and other retail products.

5. Store all custom processed animals and animal products on separate shelves while in cold storage. A "NOT FOR SALE" tag, with corresponding record number from the original tag, should be attached to any shelves or packages storing custom processed animals or animal products.

Guideline For Validating Custom Processing Animals HACCP Plans

Prerequisites and Standard Operating Procedure(s) (SOPs)

- ❑ Most recent inspection reports indicate compliance with all regulations. Pre-existing violations, which may result in biological/physical/chemical contamination of product, have been corrected.
- ❑ Instructions provided for cleaning and sanitizing all equipment used to process game animals or meat before processing domestic meat, poultry, fish, ready-to-eat foods and other retail products.
- ❑ Separate storage areas provided in cold storage unit(s) for custom processed animals and animal products
- ❑ "NOT FOR SALE" tag/label, with corresponding record number from the original tag/label, provided for shelves or containers holding custom processed animals or animal products

Hazard Analysis Included

- ❑ Microbiological contamination, such as viruses, rickettsiae, bacteria, or parasites

CCP Identified

- ❑ Receiving - tagging/labeling

Critical Limit Identified

- ❑ Carcasses or portions of carcasses immediately tagged/labeled with "NOT FOR SALE" notices

Monitoring Procedures Identified

- ❑ Every carcass, or portion thereof, visually inspected for presence of tag/label
- ❑ Person(s) identified for monitoring presence of tag/label

Corrective Actions and Documentation Procedures Identified

- ❑ Verify segregation of improperly tagged/labeled product
- ❑ Verify disposal: product of unknown origin or product contacting custom processed animal(s)
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Cause of deviation determined

Verification Process Identified (Short Term/Long Term)

- ❑ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC
- ❑ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

Records Identified

- ❑ Tag/label
- ❑ Written list of days and times when game animals are processed
- ❑ Receiving record (log book) including:
  - name and address of the owner of each carcass
  - species
  - date received
  - dressed weight
  - assigned designated carcass number to the tag
- ❑ Records/tags/labels maintained for at least 90 days
- ❑ Corrective action record

Employee Training Plan Documented (sample of training log provided)

- ❑ Employee Health and Hygiene
- ❑ Cross-contamination Prevention Procedures
- ❑ Corrective Actions
- ❑ Cleaning and Sanitizing Procedures
- ❑ Monitoring Procedures Meet Critical Limits
- ❑ Recordkeeping Requirements

Molluscan Shellfish Tanks

Public Health Rationale

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

Regulation: 4-204.110 Molluscan Shellfish Tanks

(A) Except as specified under ¶ (B) of this section, molluscan shellfish life support system display tanks may not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only.

(B) Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified in FC 8-103.10 and a HACCP plan that:

(1) Is submitted by the permit holder and approved as specified under § 8-103.11; and

(2) Ensures that:

(a) Water used with fish other than molluscan shellfish does not flow into the molluscan tank,
(b) The safety and quality of the shellfish as they were received are not compromised by the use of the tank, and
(c) The identity of the source of the shellstock is retained as specified under § 3-203.12.

Controls and Guidelines

Retail Molluscan Shellfish Tanks (Live Fish Holding)

The design and operation of a Live Fish Holding System can play a major role in the prevention of foodborne illness. Proper design will facilitate cleaning and sanitizing of the equipment. In addition, hydraulic design of the unit is important to assure an adequate quantity and quality of water for the intended purpose.

Inadequate flow or "dead spots" can lead to bacteriological growths and/or oxygen deficiency and fish mortality. Minimum turbulence will permit feces and other organic matter generated by active fish to settle out without being suspended and ingested. Use of food grade materials for all construction materials and additives will prevent possible adulteration by chemicals.

Handling Molluscan Shellfish

1. Cull out dead, cracked, and weak molluscan shellfish daily. **(CCP)**

2. Before adding molluscan shellfish to the system, make sure they are cleaned thoroughly and that you cull out all dead, cracked, and weak animals.

3. Never mix molluscan shellfish with other fish species.

4. If the tank is ever used for crab, lobster, etc. it must be sanitized before molluscan shellfish may be added. To sanitize the tank, follow the instructions for cleaning the UV bulb (adding bleach solution to tubes, etc.) At the end of the 30 minute soaking period do not open the drain. Fill tank to normal operating level with fresh water and turn system on for 30 minutes. Turn system off and thoroughly flush out tubes, bio-mix, and tank sides. Make sure all bleach smell is gone before adding molluscan shellfish.

5. Never mix lots of molluscan shellfish which come from different shipping containers and are marked with different shipping tags. If molluscan shellfish are added to a tank which already has the same species, then the two lots must be kept separated with a non-absorbent, easily cleaned divider or by the use of non-toxic, single use mesh bags. (These requirements are designed to facilitate a food poisoning investigation and/or food recall).

6. Every shipment, or portion thereof, should be visually inspected to ensure that shellfish is tagged with information as required under Section 3-202.18: Shellstock Identification. **(CCP)** In addition, shellstock tags are to be retained for 90 days from the date the container is emptied and filed in chronological order correlated to the date when, or dates during which, the shellstock are sold or served.

System Design

1. Equipment and utensils must be constructed with materials that are durable, non-absorbent, non-toxic, and easily cleanable.

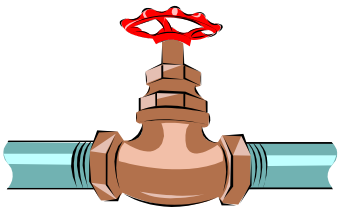
2. Hold at least 100 gallons of water per 75 pounds of shellfish.

3. Re-circulation systems should include:

   - A filtration system capable of maintaining a clean and healthy environment.
   - Refrigeration units that can maintain water temperatures between 40-60°F.
   - An accurate thermometer.
   - An adequately designed aeration system (see manufacturers instructions)
   - Units which store bivalve mollusks require a UV disinfecting unit (or similarly approved device) capable of maintaining the water quality at a bacteriological count of 2 coliform/ 100 ml or less.
   - Water must be tested upon initial set-up and on a regular basis thereafter.

4. Dead-ended pipes or hoses that could fill with stagnant water should be avoided.

5. Systems should be equipped with back-flow prevention devices to protect potable water supplies.



System Operation

1. Operational and maintenance instructions plus a notice of public health concerns should be attached to each live holding unit.

2. Marine water used in a live holding system must not be taken from an area closed to bivalve harvesting or an area subject to contamination *(i.e.* sewer/storm drain out-falls, industrial areas) or within a 125 meter radius of any docks or wharves. If artificial sea water is prepared, the ingredients must be food grade materials and the water from an approved water system.

3. Defoamers, if used, must be of food grade quality.

4. The turbidity of the water should not exceed 20 NTU.

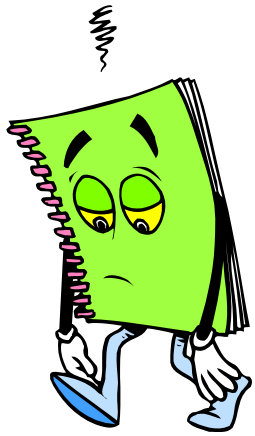
5. Product loading must not exceed the manufacturer's recommended limits.

Additional requirements for bivalve mollusks:

6. Prior to placement in tanks, all shellfish shall be washed and culled to remove dead, broken or weak animals and culled on a daily basis thereafter.

7. Bivalve mollusks must not be mixed with other fish species or share common water systems.

8. Bivalve mollusks from different suppliers, harvest areas or harvest dates must not be commingled. Vertical plastic dividers, mesh bags, etc., may be used to maintain lot identity.



Maintenance and Records

1. Designated employees should be responsible for maintenance. Maintenance instructions, operating manuals and checklists should be made available.

Maintenance procedures should include:

a) A weekly cleaning and servicing of the holding unit (draining not required) to include spray nozzles, filtration system, etc.
b) Daily check to ensure the light is functioning, cleaning the Ultra-violet disinfection system every 6-8 weeks, and replacement of the UV bulbs every 9-10 months. (Spare UV bulbs should be readily available). **(CCP)**

2. Maintenance and operational logs (water quality, temperature, etc.) are to be complete and accurate and should be kept a minimum of one year.

3. Records of each lot of bivalves (indicating where purchased and at which plant they were processed) must be kept on site for a minimum of 1 year and made available upon request.

Maintenance Guidelines

Oysters, clams and mussels in a living state must be adequately protected to remain safe, wholesome and attractive to the consumer. Federal, state and local health codes usually have specific sanitary controls and record-keeping requirements that are to be applied to the shellfish by all wholesalers and retailers. These requirements usually specify that:

- shellfish are to be stored and handled so as not to become contaminated
- storage equipment is to be properly designed, constructed, and cleaned
- different lots must be stored separately
- health officials must be able to trace a lot of shellfish to the original shipper and harvest area of origin.

Proper use of holding tanks will ensure that these requirements are met or exceeded. Therefore, the following additional operating instructions must be followed to conform to federal and state requirements.

Care of the UV Unit

1. **Clean the bulb (every 6-8 weeks)**
   The UV Unit is a white tubular appliance that is connected to the water circulation hose lines. The unit contains an ultra-violet (UV) bulb which kills bacteria as they pass by. For this reason, clean the bulb every 6-8 weeks.

2. **Drain tank**
   Do not remove bio-mix. Mix 1/2 cup bleach with one gallon fresh water. Remove spray tops from riser tubes. Pour 1/2 of bleach solution down each riser tube using funnel or container with pour spout. Leave tank drain closed and allow solution to stand in tubes for 30 minutes. Open tank drain and flush out solution by running water from hose down each riser tube. Flush system completely.

3. **Change the UV bulb (every 9-10 months)**
   Unplug unit! Remove protective end caps from chamber. Disconnect bulb-pin plugs from both ends of bulb. Remove "0" rings from each end and save for new bulb. Remove old bulb and replace with new. Replace "0" rings and reconnect plugs and end caps.

Additional System Procedures

Maintenance log

One of the welded panels on the system's base should contain a summary of critical instructions as well as a maintenance log. The log allows the establishment to track the frequency of critical maintenance procedures. The log should be filled out regularly.

Dividers

Removable dividers used in the tank to keep different lots of molluscan shellfish or different species separated must be smooth, non-toxic, non-absorbent, and easily cleaned. Dividers left in the system should be cleaned every time the system is cleaned and be washed, rinsed, and sanitized in an approved manner.

Cleaning Tank Interior

It is important that the tank interior be kept free of algae and slime build-up. To prevent this build-up, the tank interior should be wiped down with a clean rag or towel every time you clean the filter bed (at least once a week).

Troubleshooting Operational Problems

Proper maintenance is the key to the health and longevity of the aquatic animals within the tank. Routine maintenance such as dusting shelves or rotating stock needs to be done regularly. Proper cleaning of the filter system, cleaning and replacement of the ultraviolet lights and disinfection of the tank are major concerns.

Problems to look for are listed below:

1. *Foam* is caused by a build-up of organic proteins and other material in the water. Usual cause is from bleeding of an aquatic animal into the water.

    a) Remove foam by scraping off surface with fine mesh screen or siphon and vacuum.
    b) Look for cause. Remove injured animals and check for missing body parts (i.e., fins, legs, cracked or broken shells, etc.).

2. *Ammonia smell - foul odor* indicates that organics have built up to a level that anaerobic bacteria have started to digest the matter.

    a) Clean tank
    b) Clean filters
    c) Remove organic solvents
    d) Change the water
    e) Check the ultra violet light

3. *Algae* is normal when tanks are in areas with lots of natural light.

    a) Clean algae off with a clean soft cloth.
    b) Rinsing shellfish thoroughly with cold running water will remove the algae spores from their bodies.
    c) Do not use chemicals to remove the algae from tanks when animals are in the tanks.

4. *Cloudy or yellow hazy water* indicates a build-up of organic proteins (will lead to foaming).

    a) Change the filter's activated carbon unit.
    b) Check for damaged or sick animals.
    c) Check for clogged filter units or clogged air stores.
    d) Install a properly designed filter system if one is not in place.

5. *High mortality* may be caused by several reasons such as:

    a) Animals damaged or suffering from temperature shock during transportation or transfer to tanks.
    b) Toxic substance added to tank, i.e. cleaning chemicals, insect spray, non-food grade glues, non-approved algaecides.

Guideline For Validating Molluscan Shellfish Tank HACCP Plans

(UV Disinfection)

Note: All water, regardless of source, used in a recirculating water system, is required to pass through a disinfection system prior to entering the wet storage tanks.

Prerequisites and Standard Operating Procedure(s) (SOPs)

- ❑ Most recent inspection reports indicate compliance with all regulations. Pre-existing violations, which may result in biological/physical/chemical contamination of product, have been corrected.
- ❑ SOPs that prohibit commingling molluscan shellfish with other species of seafood
- ❑ SOPs for the separation of different lots of shellstock stored in the same tank.
- ❑ Personnel designated for system maintenance.
- ❑ Description of water source, treatment system and maintenance plan (equipment specifications/ manufacturer's instructions/operating manuals etc.).
- ❑ Shellstock tags to be retained for 90 days from the date the container is emptied and maintained in a manner that can facilitate tracebacks. (120 days if the state of origin labeling is different).
- ❑ Cleaning and sanitizing procedures provided. Disinfection or other water treatment activities cannot leave residues that are not Generally Recognized as Safe (GRAS)

Hazard Analysis Included

Receiving

- ❑ Pathogens from the harvest area

Culling & Ultra-violet disinfecting unit

- ❑ Elevated bacterial counts

CCP Identified

- ❑ Receiving
- ❑ Culling
- ❑ Ultra-violet disinfecting unit

Critical Limit Identified

Receiving

- ❑ Shellfish is tagged with information as required under Section 3-202.18: Shellstock Identification Storage
- ❑ Different lots of shellfish kept separated using flow-through dividers or mesh bags.
- ❑ No other species of seafood stored in molluscan wet storage tank.

Culling

- ❑ Dead or cracked shellfish discarded

UV Disinfecting Unit

- ❑ Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water.

Monitoring Procedures Identified

Receiving

- ❑ Every sack of shellstock is visually inspected for tags or labels by designated PIC
- ❑ Person(s) identified for receiving shellstock

Culling

- ❑ Tank visually inspected daily and/or when adding new shellfish, for open, cracked shells by tank operator

UV Disinfecting Unit

- ❑ Light is visually inspected daily, by tank operator, to ensure it is functioning properly
- ❑ For water that is disinfected by UV treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Method for the Examination of Water and Wastewater,* APHA.

Corrective Actions and Documentation Procedures Identified

Receiving
- ❑ Untagged sacks rejected
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Cause of deviation determined

Culling
- ❑ Culling operation initiated immediately
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Cause of deviation determined

UV Disinfecting Unit
- ❑ Bulb replaced immediately
- ❑ Shellfish moved to cold storage if problem cannot be resolved immediately
- ❑ Shellfish held pending evaluation of time/temperature exposure
- ❑ Corrective action in accordance with MA Guideline for Obtaining a Permit for Onshore Wet Storage of Shellfish
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Cause of deviation determined and recorded

Verification Process Identified (Short Term/Long Term)

Receiving
- ❑ If shellstock is received from out of state, *Interstate Shellfish Shipper's List* (ISSL) is reviewed to verify supplier as an approved source

Storage
- ❑ Thermometer calibrated monthly, or as needed

Receiving, Culling, Storage
- ❑ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC
- ❑ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

Ultra-violet disinfecting unit
- ❑ Coliform study conducted prior to final regulatory approval, when make-up water of more than 10 percent of the water volume is added, and whenever new UV bulbs are installed in accordance with the MA Guideline for Obtaining a Permit for Onshore Wet Storage of Shellfish (recirculating water systems) .
- ❑ Weekly laboratory analysis of tank water negative for coliform.

Records are Identified

Labeling
- ❑ Label/tag check record or receiving log
- ❑ Corrective actions recorded in log (sample page included)

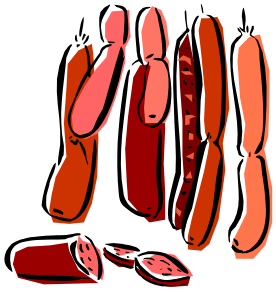
Storage
- ❑ Temperature logs (water 40-60 F)
- ❑ Corrective actions recorded in log (sample page included)

Water Testing
- ❑ All water testing reports and corrective action records retained for two years.

Employee Training Plan Documented (sample of training log provided)

- ❑ Employee Health and Hygiene
- ❑ Cleaning and Sanitizing Procedures
- ❑ Cross-contamination Prevention Procedures
- ❑ Monitoring Procedures Meeting Critical Limits
- ❑ Corrective Actions
- ❑ Recordkeeping Requirements

Smoking and Curing



Public Health Rationale

Meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices. These are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat.

The process may include dry curing, immersion curing, direct addition, or injection of the curing ingredients. Curing mixtures are typically composed of salt (sodium chloride), sodium nitrite, and seasonings. The preparation of curing mixtures must be carefully controlled.

A number of proprietary mixtures, which are uniform in composition, are available. The maximum residual sodium nitrite in the finished product is limited to 200 ppm by the USDA Food Safety and Inspection Service (FSIS). A sodium nitrite concentration of 120 ppm is usually sufficient for most purposes. Specific requirements for added nitrite may be found in USDA regulations, 9 CFR 318 and 381. It is important to use curing methods that achieve uniform distribution of the curing mixture in the meat or poultry product.

Regulation: 3-502.11 Specialized Processes

See *AFDO Retail Meat and Poultry Processing Guidelines*

Controls and Guidelines

Incorporation of Cure Ingredients

Regardless of preparation method, cure ingredients must be distributed throughout the product. Cure ingredients may be introduced into sausage products during mixing or comminution. Proper and thorough mixing is necessary whether the cure is added to the formulation in dry or solution form. Muscle cuts may be cured by immersion into a curing (pickle) solution. These methods are slow to diffuse curing agents through the product. Products must be properly refrigerated during immersion curing.

Smoking

Smoking is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking.

Smoke may be produced by burning wood chips or using an approved liquid smoke preparation. Liquid smoke preparations may also be substituted for smoke by addition directly onto the product during formulation in lieu of using a smokehouse or another type of smoking vessel.

As with curing operations, a standard operating procedure must be established to prevent contamination during the smoking process.

Fermentation and Dehydration

Meat may be fermented or dehydrated for preservation. The purpose of fermentation is to reduce the pH to below 4.6 and inhibit bacteria harmful to health as well as bacteria that can cause spoilage.

Meat products may also be cured and then dehydrated to prevent germination and growth of bacterial spores. Many fermented and dehydrated meats are made without a cooking step.

Sanitary practices in the production of these products are extremely important because *Staphylococcus aureus* can be introduced. *Staphylococcus aureus* produces an enterotoxin that is heat stable and thus will not be inactivated by subsequent cooking.

Processed pork products require treatment to destroy *Trichinella spirilla*. At retail, products which contain raw pork and which are not subsequently cooked must be produced from trichina-free certified pork or treated to destroy trichina. USDA regulations, 9 CFR 318.10(c)(3), establish various requirements for destroying trichina in pork by heating, freezing, drying, or smoking.

Some fermented and dry cured products are processed without cooking. The labeling for these products should include instructions to the consumer to cook thoroughly before consumption.

Dedicated Area/Restricted Access

All aspects of curing operations must be conducted in an area specifically designated for this purpose. There must be an effective separation to prevent cross contamination between raw and cooked foods or cured and uncured foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in curing foods.

Equipment Cleaning and Sanitizing

The procedures for cleaning and sanitization must be accomplished according to parts 4-6 and 4-7 of the Food Code.

AFDO - Retail Meat and Poultry Processing Guidelines

Introduction

The Association of Food and Drug Officials (AFDO) is pleased to provide these guidelines in response to requests from state and local government to provide guidance for the processing of meat and poultry at retail.

These guidelines provide sound scientific support for the production of unique meat and poultry products such as dry and semi-dry fermented sausage, meat jerky and cured and smoked meat and poultry.

The guidelines have been reviewed and approved by members of the AFDO Retail Food Committee, the AFDO Board of Directors and the U.S. Department of Agriculture.

I. Ground Meats

A. Definitions

1. **"Beef Pattie Mix"** or **"Beef Patties"** if in pattie form, means chopped, or mechanically separated ground beef or partially defatted beef fatty tissue with or without the addition of beef fat. Binders or extenders may be used without added water or with added water only in amounts so that the products characteristics are essentially that of a meat pattie.

2. **"Comminuted"** means reduced in size by methods including chopping, flaking, grinding or mincing.

3. **"Grinder"** means a piece of equipment used to cut meat into small pieces. The meat is fed from a hopper, passed along a cylinder with an auger or worm to a perforated plate where it is sliced away by revolving blades.

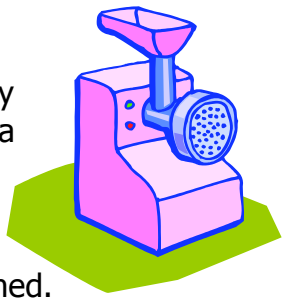
4. **"Ground Beef"** means chopped or ground beef with or without seasoning and without the addition of beef fat, as such, shall not contain more than 30% fat and shall not contain added water, phosphates, binders or extenders.

5. **"Ground Poultry Meat"** means chopped or ground poultry without the addition of water, cereal, soy derivatives or other extenders and with no more than 15% skin.

6. **"Hamburger"** means chopped fresh or frozen beef with or without the addition of beef fat, as such, and/or seasoning, shall not contain more than 30% fat, and shall not contain added water, phosphates, binders or extenders.

B. Grinding

1. Whenever a grinder is temporarily stored with the intent of using it again within the next two hours, the meat contact surfaces should be stored under refrigeration at a temperature of 41° F or less.



2. Grinding equipment shall be completely disassembled and cleaned by washing, rinsing and use of an approved sanitizer after each use or a maximum of every ten hours.

3. If the species of meat being ground is changed from one batch to the next, the entire grinding assembly must be dismantled and cleaned.

C. Time-Temperature Control During Grinding and Trimming

Trimmings to be used for ground meat shall be held at 41° F or less (product temperature) during the trimming process. Ground meat and poultry shall be held at 41° F or less at all times during grinding, storage or display.

D. Labeling Ground Beef

1. The common or usual name of any added ingredient shall be listed on the package label in decreasing order of predominance or on a placard when displayed in bulk.

2. An added descriptive name may be used where the ground meat is prepared entirely from a specific cut such as chuck, round or sirloin (example: ground beef sirloin). When beef trimmings are used in the mixture, it may only be labeled as ground beef or hamburger.

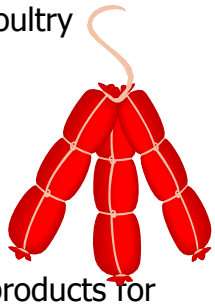
3. When beef check meat (trimmed beef checks) is used in the preparation of chopped beef, ground beef or hamburger the amount of cheek meat shall be limited to 25% and must be declared in an ingredient statement on the label. If more than 25% is used the product name and ingredient statement must reflect such fact.

4. The fat content or lean content shall be clearly indicated on the label. The fat content shall not exceed 30%. Whenever the terms "lean," "extra lean" or "reduced fat" are used, the product and labeling must be in compliance with NLEA requirements listed in the Code of Federal Regulations.

5. "Previously Frozen" must be labeled on the package, container or wrapping if a meat/meat food product or poultry/poultry food product has been frozen prior to sale.

6. The label shall contain a code date to identify the batch or lot.

7. A "Safe Handling Statement," as defined by USDA Meat and Poultry Regulations 9 CFR 317.2(1) and 381.125, shall be fixed to the package where it is easily visible to the consumer.



II. Curing and Smoking

A. Definitions

1. **"Acceptable Product List"** means a list of meat or poultry products for which a HACCP Plan has been approved by a process authority.

2. **"Casings"** mean natural animal stomachs, intestines or bladders or manufactured casings of cellulose or collagen, which are used to contain comminuted meat, or poultry product mixtures for sausages.

3. **"Cold Smoking"** means a smoking process used to apply smoke or a smoke flavor at or near ambient temperature to food products not sufficiently darkened or flavored in the original cooking process.

4. **"Curing"** is a process of preserving meat by the application of salt, nitrite and seasonings to meat and is characterized by the interaction of nitrite and meat pigments resulting in the development of a "cured" pink color.

5. **"Cure Accelerator"** means compounds such as ascorbic acid or erythorbic acid or their derivatives, sodium ascorbate and sodium erythorbate as defined for use in 9 CFR 318.7(c)(4), which shorten the time required for the distinctive pink color to develop in cured meat and poultry products.

6. **"Injection"** means the process of transferring a curing solution into a whole muscle meat using a needle or group of needles connected to a brine source.

7. **"Massaging"** means subjecting meat chunks to a mechanical treatment to facilitate protein extraction from muscle fibers. This process accelerates the even dispersal of cure solution and increases yield.

8. **"Process Authority"** is a person or organization with expert knowledge in meat or poultry production, process control and relevant regulations.

9. **"Showering"** means a potable water spray with or without liquid smoke in the smoke house which, depending on when the water spray is applied, maintains humidity, flavors, decreases cooking time, promotes rapid cooling or reduces casing shrinkage.

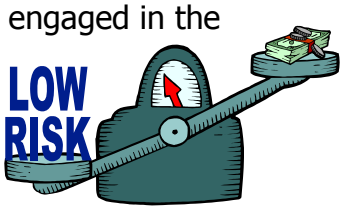
10. **"Smokehouse"** means a piece of equipment or room sized enclosure used to conduct the smoking and cooking process which has a smoke source, adequate ventilation, heat and humidity source if necessary, approved plumbing and waste lines if necessary, support structures for the food products to be smoked and a method to determine internal product temperature.

B. Trained Employees

All employees engaged in the curing and smoking process shall receive training and demonstrate familiarity with the curing and smoking processes as well as the associated hazards.

C. HACCP Plan

Each retail food establishment that engages in the curing and smoking process must have a HACCP plan validated by a process authority. This HACCP plan must be made available to the regulatory authority for review and audit. The HACCP Plan must contain process flow charts for each category of product, recipe formulations for each product that is cured and/or smoked, identified hazards, critical control points, critical limits, monitoring procedures, corrective action and verification steps. It must include a list of acceptable products, which have received approval under the HACCP Plan. It shall also contain a description of the training course content for employees engaged in the curing and smoking operation.



D. Equipment and Materials

1. A calibrated automatic recording thermometer with internal product temperature probes or calibrated metal-stemmed thermometer shall be available and used when product is smoked.

2. Calibrated and certified scales shall be used to weigh any curing compound, cure accelerator or other additive, provided it has not already been pre-measured and weighed.

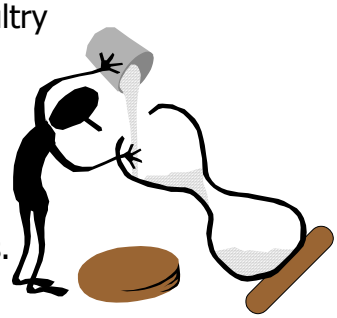
3. Tumble massagers facilitate the extraction of salt soluble proteins and accelerates the distribution of cure solution in chunks of meat. Massaging must be done under refrigeration, recommended at 33° to 36° F.

4. All equipment coming in contact with meat products must be fully cleaned by washing, rinsing and use of an approved sanitizer.

5. A smoke generator attached to a smokehouse may only use materials approved by USDA, FDA or other regulatory agencies. These include non-resinous hardwoods, hardwood sawdust, redwood, mesquite wood, corncobs and natural liquid smoke.

6. Natural or artificial casings for sausage, loaf or chub forming must be sanitary and may not be stripped for reuse with another batch or lot. The casings may be salted or unsalted, colored or shirred, that is, pleated or compressed for easy application to the stuffing horn.

7. Curing or smoking may not be used to salvage meat or poultry that has excessive bacterial growth or spoilage.



E. Time-Temperature Control During Curing

1. The curing process using immersion and injection shall be done so that product temperature remains at 41° F or less.

2. Meat and poultry products, as well as natural and artificial casings during soaking shall be stored at 41° F or less.

3. The internal temperature of any smoked meat or poultry or smoked meat or poultry product shall comply with cooking requirements for that product, with the exception that:

   a. cold smoking is a smoking process used only to apply smoke color or flavor at ambient temperature to food products, and

   b. when a cold smoking process is used for cosmetic purposes, that is, to add smoke color or flavor to pre-cooked product, it must be of such duration that the internal product temperature remains at or below 41° F.

F. Curing Process

1. Use of curing agents, curing accelerators, and other additives shall be according to 9 CFR 318.7, Approval of Substances for Use in the Preparation of Products, and 9 CFR 381.147, Restrictions on the Use of Substances in Poultry Products.

2. The formulation and preparation procedure must be documented by lot.

G. Curing Methods

1. Dry curing means all surfaces of the meat are rubbed and covered with a dry cure mixture at intervals of sufficient frequency to assure cure penetration.

2. Dry salt curing is a modification of the dry curing method where the product may be injected with cure solution directly into the muscle in addition to dry curing.

3. Immersion curing means the product is immersed in a strong pickle or brine solution. Immersion curing solutions shall be discarded after each use except when they remain with the same batch or lot during the entire curing process.

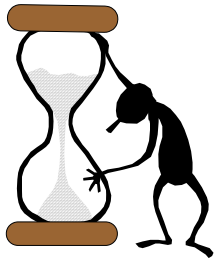
4. Injection curing introduces the curing solution into the muscle meat through hollow needles.

    a. Stitch pumping injects the curing solution deep into the muscle with a single orifice needle.

    b. Spray pumping injects the curing solution using a needle with many orifices to allow more uniform distribution of the solution.

    c. Artery pumping injects the curing solution into the natural circulatory system of the meat.

    d. Machine pumping, similar to stitch pumping, injects the curing solution using 10 or more needles. Sometimes spring-loaded needles are used for bone-in products to prevent breaking the needles products to prevent breaking the needles.



H. Time-Temperature Control During the Smoking Process

1. The hot smoking process shall be considered equivalent to a cooking process and be required to meet all internal time-temperature cooking requirements. This information shall be documented for each lot.

2. Cold smoked meat and poultry products shall be processed at or near ambient temperature so that the internal product temperature does not rise above 41° F. The product and air temperature shall be monitored at all times.

3. Hot smoked meat and poultry products shall be cooled from 140° F to 70° F within 2 hours and to 41° F or less within an additional 4 hours.

    a. If cold water showering is used to rapidly drop product temperature after smoking, it must be potable water, should contain a chlorine residual, may not be re-circulated unless by an approved method, and if reclaimed, must be discarded daily.

    b. Cooling times and temperatures must be documented for each lot, but in all cases, internal product temperature must cool from 140° F to 70° F within 2 hours and from 70° F to 41° F or below within an additional 4 hours.

I. Storage of Smoked Product

Ready-to-eat smoked product must be stored in a manner and location to prevent cross-contamination or adulteration.

III. Dry and Semi-Dry Fermented Sausage

A. Definitions

1. **"Dry Fermented Sausage"** means a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and is then dried to remove 25-50% of the moisture to have a moisture/protein ratio in compliance with USDA requirements. Dry fermented sausages include hard salami, Genoa salami, and pepperoni.

2. **"Fermentation Culture"** means an active and pure culture of one or more bacteria, which effects the rapid pH drop in dry and semi-dry fermented sausages.

3. **"Semi-Dry Fermented Sausage"** means a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and undergoes up to 15% removal of moisture during the fermentation/heating process. Semi-dry fermented sausages include summer sausage, thuringer, cervelat and Lebanon bologna.

B. Validation of Processing Procedure for Dry and Semi-Dry Fermented Sausages

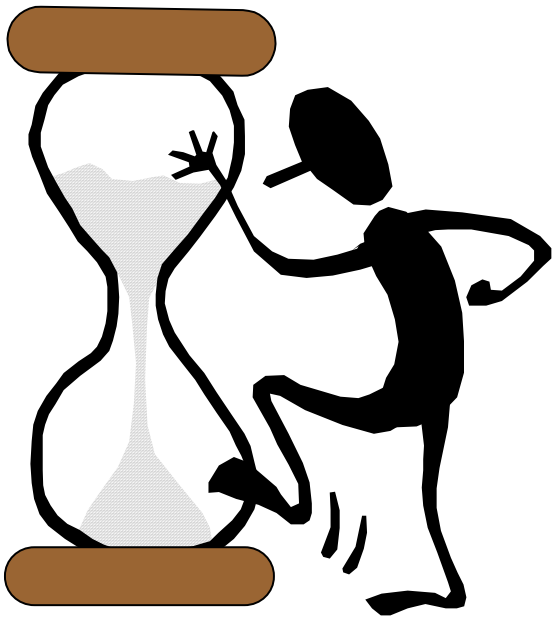
In light of foodborne outbreaks of Ecoli *0157:H7* linked to dry fermented ready-to-eat sausage products, all procedures for dry and semi-dry fermented sausages must be validated to show products achieve a 5-log reduction of Ecoli *0157:H7.* Full documentation is required. This can be accomplished by using one or more of the following options:

1. Submit the processing procedure to a recognized process authority for validation.

2. Design and conduct validation studies utilizing a laboratory that is certified for testing pathogenic bacteria in meat and poultry products including any non-food manufacturing bio-safety level II facility.

3. Modify processing procedures to include a moist heating Step after fermentation but prior to drying. The moist heating can be accomplished by using a sealed oven or steam injection to raise the relative humidity above 90% throughout the cooking process and meet one of the following time/temperature requirements:

Minimum ° F Internal Temperature	Minimum Holding Time at that Temperature
130	121 min.
131	97 min.
132	77 min.
133	62 min.
134	47 min.
135	37 min.
136	32 min.
137	24 min.
138	19 min.
139	15 min.
140	12 min.
141	10 min.
142	8 min.
143	6 min.
144	5 min.
145	4 min.
146	182 sec.
147	144 sec.
148	115 sec.
149	91 sec.
150	72 sec.
151	58 sec.
152	46 sec.
153	37 sec.
154	29 sec.
155	23 sec.
156	19 sec.
157	15 sec.
158	0 sec.
159	0 sec.
160	0 sec.



4. Examples of processes that yield a 5 D or more reduction of Ecoli 0157:H7: (from "Dry Fermented Sausages and E. coli *0157:H7*" 1997 by the Blue Ribbon Task Force of National Cattlemen's Beef Association.)
    a. Ferment at 90° F to pH 5.3 and apply cook, then dry for >7 days (large casing).
    b. Ferment at 90° F to pH 4.6 and hold at 90° F for _>6 days (small casings).
    c. Ferment at 90° F pH 4.6 and apply cook (small and large casings)
    d. Ferment at 110° F to pH 4.6 and hold at 110° F for _>4 days (small and large casings).

5. Initiate a hold and test program unless the source of the ingredients has been certified pathogen free. This involves the holding and testing of all batches of dry and semi-dry sausages. Samples must be submitted to a laboratory that is certified for testing pathogenic bacteria in meat and poultry products.

6. Implement a HACCP plan combined with Good Manufacturing Practices (GMPs) for fermented sausage, including raw batter testing and documentation of at least a 2 D lethality of Ecoli 0157:H7 between stuffing and shipping.

    a. An acknowledged analytical method equivalent to that used by USDA/FSIS must be implemented in the raw batter testing.

    b. The sample size and composting procedure must ensure a detection level of 1 E. coli/gm. (It is recommended that 15-25gm. samples be taken from across the lot. These could then be composited into 575gm analytical samples.)

    c. The definition of a "lot" for the purposes of sampling must be statistically sound.

    d. GMPs must be applied.

    e. The process must also address other hazards, e.g., *Trichinella* and *Staphylococcus.*

    f. A procedure for dealing with lots from positive batter samples must be defined in the HACCP plan. At a minimum, all positive lots must be subjected to conditions that will provide a total 5 D process.

C. Fermentation Cultures

An active fermentation culture is necessary to produce lactic acid which lowers the meat pH and aids in inhibiting staphylococcal growth during the warm-temperature processing (fermentation) phase, contributes to the process' lethality toward bacterial hazards, contributes to the stability of the finished product, and aids in releasing moisture from the meat during the drying phase for dry sausages.

1. Starter Culture

If a commercially prepared fermentation culture is used, any special handling instructions specified by the manufacturer regarding frozen or refrigerated storage and other factors must be observed.

2. Back Inoculation

If a back inoculum from a previously fermented and controlled mother batch is used, the mother batch shall have attained a pH of 5.3 and shall be monitored on a regular basis for lactic producing bacteria and coagulase positive Staphylococci.

3. Enrichment

Reliable enrichment requires both time and control. USDA ARS scientists established that aging salted meat for at least 10 days at 40° F was required. The added salt could be no more than 3.5% salt and no less than 2% salt. Since that research, many packers have implemented bactericidal treatments for carcasses. These treatments may affect the reliability of traditional enrichment procedures.

D. Fermentation Time-Temperature Control

Once the sausage pH reaches 5.3, during lactic acid bacterial fermentation, the potential for staphylococcal toxin formation is effectively controlled. Because staphylococcal growth is directly proportional to temperature, the time to reach pH 5.3 at higher temperatures must be shorter. In 1982, the AMI developed the following degree-hour strategy for controlling staphylococcal toxin formation, which has proven to be effective.

1. Degrees/Hours Defined*

a. Fewer than 1200 degree/hours when the highest fermentation temperature is less than 90° F.

b. Fewer than 1000 degree/hours when the highest fermentation temperature is between 90° F and 100° F.

c. Fewer than 900 degree/hours when the highest fermentation temperature is greater than 100° F.

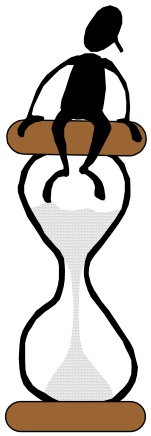
Note: Degrees are measured as the excess over 60° F at which staphylococcal growth effectively begins. Degree/hours are the product of time in hours at a particular temperature and the "degrees." Degree/hours are calculated for each temperature used in the process. The limitation of the number of degree/hours indicated in a, b, and c depend upon the highest temperature in the fermentation process prior to the time that a pH of 5.3 or less is attained.

Processes exceeding 89° F prior to reaching a pH of 5.3 are limited to 1000 degree/hours; processed exceeding 100°F prior to reaching pH 5.3 are limited to 900 degree/hours.

2. Temperature measurements should be taken at the surface of the product. Where this is not possible, fermentation room temperatures should be utilized.

3. Constant Temperature Processes. The time temperature relationships for constant temperature processes, predicated on fermentation room temperatures, are as follows:

Degree/Hours	Temperatures (°F)	Allowed Hours
1200	75	80
1200	80	60
1200	85	48
1000	90	33
1000	95	28
1000	100	25
900	105	20
900	110	18



Examples of Constant Temperature Processes

Process A Constant 80° F temperature for 55 hrs. with pH decline to 5.3
Degrees: 80 - 60 = 20
Hours: 55
Degree/Hours: (20) x (55) = 1100 degree/hours

Process A Passes

Process B Constant 90° F temperature for 40 hours with a pH decline to 5.3
Degrees: 90 - 60 = 30
Hours: 40
Degree/Hours: (3b) x (40) = 1200 degree/hours

Process B Fails (Limit: 1000 degrees/hours)

4. Variable Temperature Processes. In testing each process, each step-up in the progression is analyzed for the number of degree/hours it contributes, with the highest temperature used in the fermentation process determining the degree/hour limitation as follows:

Process C

Hours	Temperature	Critical Temp. Adjustment	Degrees	Degree/Hours
10	75	75-60	15	150
10	85	85-60	25	250
16	95	95-60	35	560

pH = 5.3 **Total = 960**

Process C Passes

Process D

Hours	Temperature (°F)	Critical Temp Adjustment	Degrees	Degree/Hours
10	75	75-60	15	150
10	85	85-60	25	250
18	98	98-60	38	684

pH = 5.3 **Total = 1084**

Process D Fails (The limit is set at 1000 degrees/hours for times and temperatures and it has taken 1084 degrees/hours to attain pH5.3.)

5. Lots Falling Outside Limitations

Once a processing schedule has been developed which meets these criteria, pH readings from each lot produced must be taken to assure that the product pH continues to develop normally. It is important that all pH readings are recorded before the product surface temperature reaches 110 degrees and/or before the degree/hour limitations have been reached. If the pH has not reached 5.3 by the time the limitations are met, samples should be taken from the fermentation room before the temperature is advanced. It is recommended that one sample be obtained from each mixer/batch of product.

IV. Jerky

A. Definitions

1. **"Jerky"** means a product made from animal flesh that has been cut into long slices or strips and dried.

2. **"Formed Jerky"** means a product made from animal flesh that has been shredded or ground and molded into its final shape before drying, and may or may not contain extenders.

3. **"Extenders"** are any materials such as textured soy protein or cereals that are added to the ground or shredded animal flesh and must be properly declared in the labeling of the product.

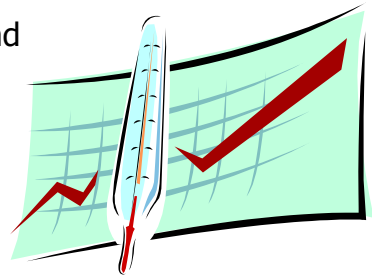
4. **"Marinade"** means to soak meat in a sauce to enrich its flavor, to tenderize or enhance its shelf life

5. **"Species Name"** jerky shall be manufactured solely from the flesh of the named animal species, otherwise "Species Name Flavored" jerky shall be the product label.

B. Processing Methods

1. If the same rooms and equipment are used for preparation and packaging, all process ware and food contact surfaces used for slicing of meat and poultry and placing in drying room or dehydrators shall be cleaned and sanitized before any finished product is packaged.

2. The establishment shall facilitate the inspection and monitoring of the treatment process by providing appropriate time and temperature recording equipment.



3. The establishment shall record the time, temperature and other critical process parameters for each lot of product produced.

4. The establishment shall have on file on site, a description of the current processing method for each product produced. The processing method description shall include a description of:

   a. Handling procedures for meat ingredients including maximum time and temperature exposures during thawing, trimming, curing, slicing, grinding, shredding, marinating, curing, and any other preparation steps or other applicable product factors;

b. A procedure for identifying a product lot during processing, its lot identification codes, and how the finished product package codes can be identified with a specific production lot. The establishment shall divide production lots into one day time increments or less;

c. Procedures used to comply with the treatment process; of the treated product; and

d. The equipment and procedures used for measuring and recording time and temperature required by the treatment used by the establishment. The measuring devices shall be both readable and accurate within plus or minus 3°F and 1 minute.

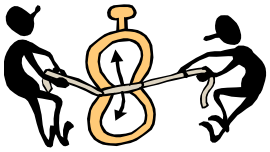
e. For shelf stable products, the procedures and control program to ensure the product meets the requirements for shelf stability.

5. All products shall be heated so that all parts reach the temperatures specified below:

a. Beef shall be preheated to 160°F before drying at 140°F for 6-10 hours.

b. Poultry, pork products, and all other meats shall be heated to at least 165°F for 15 seconds within 3 hours or less.

Time as a Public Health Control



Public Health Rationale

The Food Code permits the use of time, rather than time and temperature, as a public health control when the potentially hazardous food (PHF) will be cooked and/or held for immediate consumption. However, these foods may only be stored without temperature control for up to 4 hours, after which they must be discarded or consumed.

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during its equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings.

When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Regulation: 3-501.19 Time as a Public Health Control

If time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption:

1. The food shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the food is removed from temperature control,
2. The food shall be cooked and served, served if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control,
3. The food in unmarked containers or packages or marked to exceed a 4 hour limit shall be discarded, and
4. Written procedures shall be maintained in the food establishment and made available to the regulatory authority upon request, that ensure compliance with:
   a. Subparagraphs (A)(1)-(4) of this section, and
   b. § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control.

Except that, in a food establishment that serves a ***highly susceptible population***, time only, rather than time in conjunction with temperature, may not be used as the public health control for raw eggs.

Controls and Guidelines

Holding Hot Food without Temperature Control

When food is cooked according to Food Code recommendations and is then kept at room temperature for 4 hours before discarding, spore forming organisms *Clostridium perfringens* and *Bacillus cereus* are of primary concern.

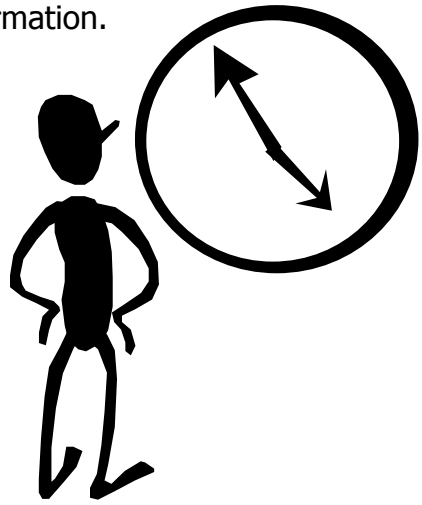
This is because food cooked according to Food Code guidelines should be free of vegetative cells. However, the heat requirements are not sufficient to kill spores of *C. perfringens* or *B. cereus* and may actually serve as a heat shock that activates the spores.

B. cereus is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. *C. perfringens* is found commonly in outbreaks attributed to inadequate hot holding of meat and poultry.

Holding Cold Food with Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, *Listeria monocytogenes* is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of *L. monocytogenes* warrants concern for potentially hazardous RTE foods.

Salmonella is also a concern especially with products containing eggs. However *L. monocytogenes* grows more rapidly than *Salmonella* at refrigeration and room temperatures. By ensuring minimal *Listeria* growth in food, the threat from *Salmonella* would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow *B. cereus* to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.



Guideline For Validating Time as a Public Health Control (TPHC) Plans

Prerequisites and Standard Operation Procedure(s) (SOPs)

- ❑ Most recent inspection reports indicate compliance with all regulations, particularly employee health and hygiene. Any pre-existing violations, which may result in biological, physical or chemical contamination of product, have been corrected.
- ❑ Includes cooling standard operating procedures (SOPs) for potentially hazardous food (PHF) that is prepared/cooked and cooled prior to TPHC.
- ❑ Includes SOP to prevent contamination during preparation and display.

Food Item Identified

- ❑ Time as a Public Health Control is not permitted in take-out operations, nor is it accepted in a food establishment that serves a ***highly susceptible population***.

Hazard Analysis Included

- ❑ Plan identifies growth of bacteria/ production of toxins.

Critical Control Point Identified

- ❑ Holding

Critical Limit Identified

- ❑ Plan does not exceed 4 hours.

Monitoring Procedures Identified

- ❑ States how food is marked or identified to indicate time is 4 hours past time removed from temperature control.
- ❑ States how food is cooked and served, served if ready-to-eat (RTE) or discarded within 4 hours.
- ❑ States how food in unmarked containers or packages or, marked to exceed a 4 hour limit will be discarded.

Corrective Actions Identified

- ❑ Delineates method by which food in unmarked containers/packages, or marked to exceed a 4 hour limit, will be discarded.
- ❑ Describes corrective action (beyond discarding) to be taken time exceeds 4 hour limit.
- ❑ Corrective actions recorded in log (sample page included)
- ❑ Cause of deviation determined

Verification Process Identified (Long and Short Term)

- ❑ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC
- ❑ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

Records are Identified

- ❑ Corrective actions recorded in log (sample page included)

Employee Training Plan Documented (sample of training log provided)

- ❑ Employee Health and Hygiene
- ❑ Cleaning and Sanitizing Procedures
- ❑ Cross-contamination Prevention Procedures
- ❑ Monitoring Procedures Meeting Critical Limits
- ❑ Corrective Actions
- ❑ Recordkeeping Requirements

Preventing Contamination from Hands

Public Health Rationale

The CDC now estimates that:

- Norwalk-like viruses are the leading cause of foodborne illness in the U.S.
- Hands are the most important means by which enteric viruses are transmitted
- Contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks.

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause. Most of these outbreaks:

- Involve enteric, i.e., fecal-oral agents
- Organisms that employees were shedding in their stools at the time the food was prepared
- Poor or nonexistent handwashing procedures on the part of food handlers
- Infected cuts, burns, or boils on
- Viral, bacterial, and parasitic agents can be involved

Regulations require several methods of preventing the spread of foodborne disease by this mode of transfer:

- Prohibit food workers from preparing food when they are infectious
- Require thorough and frequent hand washing
- Prohibit bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step)
- Provide a barrier when handling ready-to-eat foods (i.e., spatulas, tongs, single-use gloves, or dispensing equipment)

Any alternative to this requirement must convincingly address how food employees will be managed to preclude food contamination and how management will ensure that thorough handwashing occurs after employees use the toilet.

Regulation: 3-301.11 Preventing Contamination from Hands

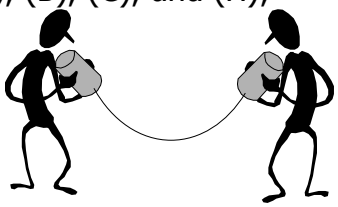
Except when washing fruits and vegetables as specified under FC 3-302.15, or *when otherwise approved* , food employees may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves or dispensing equipment.

Note: *Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves. Therefore, single-use natural rubber latex gloves are not recommended in food establishments.*

Controls and Guidelines

I. Requirements prerequisite to consideration of alternatives include compliance with all Food Code provisions, particularly those related to:

A. Demonstration of Knowledge - specifically ¶¶ 2-102.11(A), (B), (C), and (H);



B. Duties of the Person in Charge - specifically ¶ 2-103.11(D);
C. Employee Health regarding:

1. Reporting of diseases and medical conditions, and
2. Exclusions and restrictions, i.e., that food employees (including applicants to whom a conditional offer of employment has been made) report their health status as specified in Section 2-201.11; ill food employees are restricted or excluded as specified in Section 2-201.12; and the exclusions and restrictions are removed as specified in Section 2-201.13;

D. Personal Cleanliness, i.e., handwashing procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in Section 2-301.14, including after using the toilet and between tasks that may re-contaminate the hands; and

E. Hygienic Practices as specified in Part 2-4.

II. FDA recommends that the acceptability of an alternative to no bare-hand contact should be based on evidence that at least the following are addressed:

A. Why the operator of the food establishment is unable to comply with the Code requirement in ¶ 3-301.11(B);

B. How the alternative practices and procedures will control the hazard through an active managerial control program. Such a program includes monitoring and verifying the institution of the prerequisite requirements described in Part I above and satisfies the following:

1. The public health hazard associated with bare-hand contact specific to the food establishment operation is identified and understood. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

2. The ready-to-eat foods that will be contacted with bare hands are identified and both procedures and practices are in place so that food employees wash their hands before returning to their work station and cross-contamination from touching raw and ready-to-eat food is precluded.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

3. Institution of an effective training program for food employees which emphasizes not working when ill with any of the symptoms of foodborne illness, and explains good hygienic practices, proper handwashing procedures, and safe food preparation procedures. This should include a documented training plan that specifies how management responsibility for training has been designated, training program content, and the frequency of administration including periodic refresher sessions.

C. The alternative should clearly include monitoring, documentation, and verification to ensure that the practices and procedures are followed. Corrective actions need to be predetermined for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

III. Documentation of the practices, procedures, and corrective actions related to an alternative to no bare-hand contact with ready-to-eat food needs to be maintained and readily available at the food establishment at all times for use by the person-in-charge and for review by the regulatory authority.

IV. The regulatory authority should also consider industry's *elective* use, managerial control, and monitoring and verification of additional preventive measures used in tandem with the aforementioned interventions which could include one or more of the following:

A. Vaccination against hepatitis A for food employees including initial and booster shots or medical evidence that a food employee has had a previous illness from hepatitis A virus;
B. Double handwashing;
C. Use of nail brushes;
D. Use of an FDA-accepted hand sanitizer after handwashing, i.e., approved as safe for application to human skin and safe as an indirect food additive, or exempted as a food additive under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles; and
E. Motivation for food employees not to work when they are ill.

Guideline For Validating Alternative Bare Hand Contact Plans

Prerequisites

- ❑ Most recent inspection reports indicate compliance with all regulations, particularly those relative to person in charge (PIC) knowledge and employee health and hygiene. Any pre-existing violations, which may result in biological, physical or chemical contamination of product, have been corrected.
- ❑ Standard operating procedures (SOPs) for employee health and hygiene provided.
- ❑ SOPs to prevent cross-contamination of RTE after handling raw or undercooked animal foods.

Food/Process Identified

- ❑ Food employee (position)
- ❑ Food preparation/process
- ❑ Work area

Hazard Identified

- ❑ Bacterial, viral and parasitic contamination of ready-to-eat (RTE) foods from food employee's hands.

Critical Control Point Identified

- ❑ Bare Hand Contact with RTE Foods

Critical Limits Identified

- ❑ Food employees who are symptomatic (nausea, fever, diarrhea, vomiting) or diagnosed with a disease transmissible through food excluded from handling food
- ❑ Food employees not permitted to touch RTE food before washing hands when returning to their work station and in accordance with the Food Code.

Monitoring Procedures

- ❑ Monitoring procedures for handwashing practices/facilities identified.

Corrective Actions (Long and Short Term)

- ❑ Corrective actions identified should RTE food become contaminated by a food handler
- ❑ Corrective actions identified if food handler(s) observed demonstrating unacceptable health and hygiene practices
- ❑ Emergency physical barriers available (i.e. acceptable single-service gloves)

Verification Process Identified (Long and Short Term)

- ❑ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC
- ❑ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

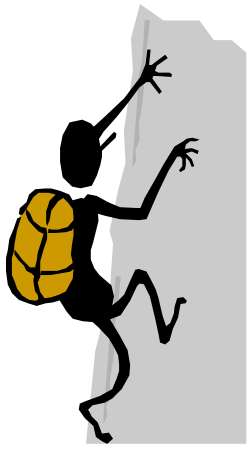
Records are Identified

- ❑ Monitoring and corrective actions recorded in log (sample page included)

Employee Training Plan Documented (sample of training log provided)

- ❑ Employee Health and Hygiene
- ❑ Cleaning and Sanitizing Procedures
- ❑ Cross-contamination Prevention Procedures
- ❑ Monitoring Procedures Meeting Critical Limits
- ❑ Corrective Actions
- ❑ Recordkeeping Requirements

Module 4 VALIDATING AND VERIFYING THE HACCP PLAN



Objectives

After this session, you will be able to:

1. Explain the difference between validation and verification.
2. Validate a HACCP plan using model forms.
3. Provide examples of verification procedures to ensure effective implementation of a validated plan.
4. Create a field verification report form to use when auditing an establishment with a validated HACCP plan.
5. Identify appropriate intervention strategies when a HACCP system is out of compliance with approved procedures.

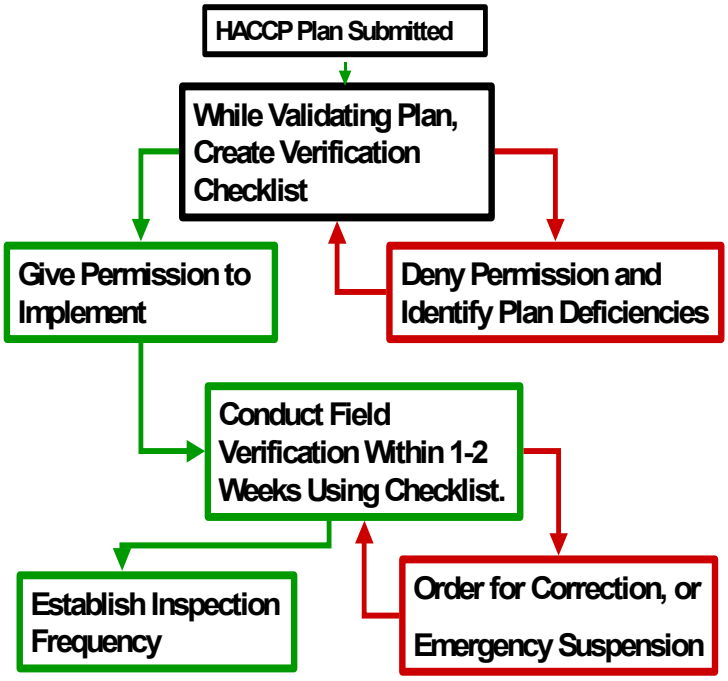
Key Terms

Validation
Validation is that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

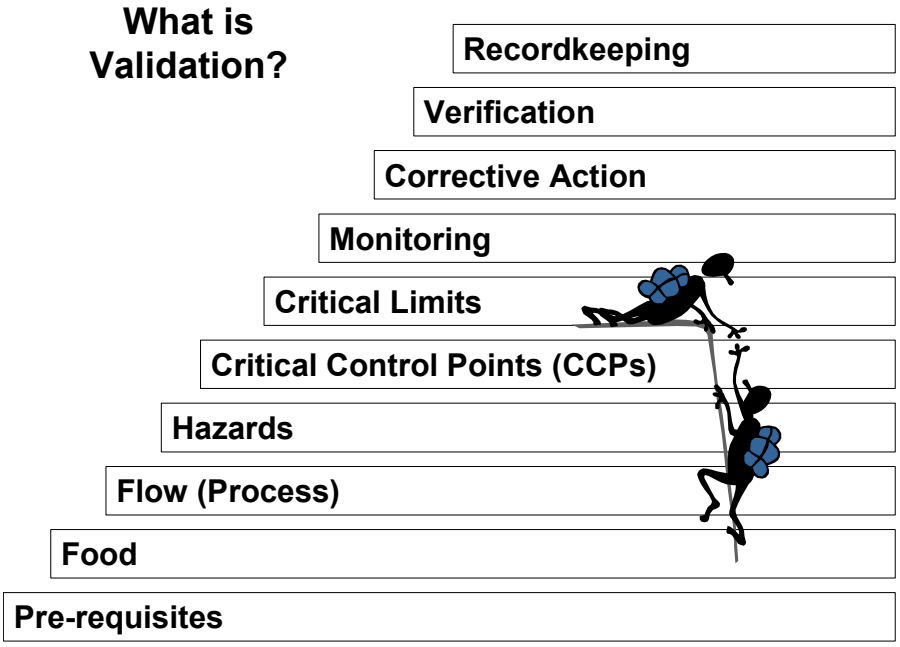
Verification
Verification means those activities other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

The HACCP Plan Approval Process

Approving a HACCP plan requires both validation and on-going field verification by the regulatory authority. Below is a model flow chart of that process.



Regulatory Approval = Validation + Verification



The Validation Process

Validation is the process of making sure that a HACCP plan, as designed, is effective in controlling hazards that may result in illness or injury. The validation process primarily involves reviewing a plan to ensure that:

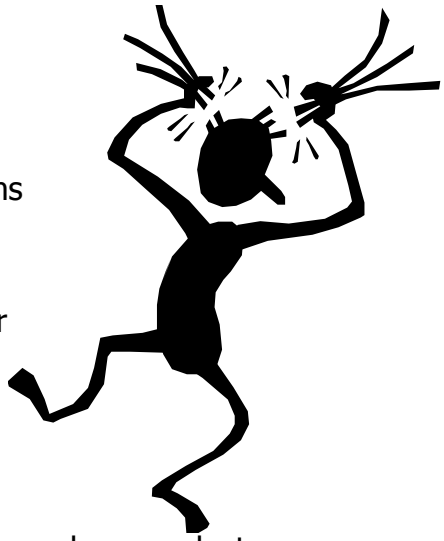
1) all of the necessary components of the written plan have been included, and that
2) the information and protocols are effective in preventing, eliminating or significantly reducing the hazards, if properly implemented.

Industry has the primary responsibility for validating their HACCP plans to ensure that all components have been included in the plan and that it can effectively control the identified hazards as designed. The regulatory authority is responsible for reviewing and validating mandated plans prior to implementation and approval.

Before validating the HACCP plan(s), the regulator should review the compliance history of the food establisment to ensure all HACCP prerequisites have been addressed (SOPs, GRPs).

When validating a plan, the reviewer is using the principles of HACCP to verify that items, including but not limited to the following, have been properly identified:

- Product or process (flow chart)
- Hazards
- Selection of CCPs
- Critical limits, monitoring procedures, corrective actions and verification procedures for each CCP selected
- Verification (validation) procedures to ensure that the plan is updated and validated as needed by the PIC or HACCP plan administrator
- Recordkeeping procedures and forms
- Employee training



In some cases it may be necessary to request additional information such as product formulation, physical facility layout, standard operating procedures and scientific documentation or laboratory data for performance standards.

Written HACCP Plan Review

The regulatory review of the written HACCP plan should be carried out by the regulator to verify that each HACCP plan is complete. The model *HACCP Plan Review Application*, which is to be completed and signed by the operator, can be used by the regulatory authority to facilitate the validation process (see Appendix A).

In order for a documented HACCP plan to be considered complete, it must be dated and signed by the designated person in charge or HACCP coordinator. It must also meet all regulatory requirements and include all required components of a HACCP plan.

When any section of the written plan is found to be incomplete, the deficiencies should be described in the "Comments" section of the *HACCP Plan Review Application*. Reasons for noted deficiencies (i.e. regulations, laboratory results, scientific data, etc.) should also be included. When all the items on the HACCP plan have been evaluated, the overall assessment of the written plan is complete.

If the HACCP plan documentation package is found to require further information or modification, the components, which are not acceptable, should be returned to the establishment with a cover letter explaining the deficiencies.

The establishment is responsible for correcting all deficiencies and resubmitting the amended HACCP Plan to the regulator for follow-up review.

When the regulator is satisfied that all deficiencies have been corrected, or that the initial plan is acceptable, and the operator has informed the regulatory authority of the implementation date, the HACCP plan validation process is complete.

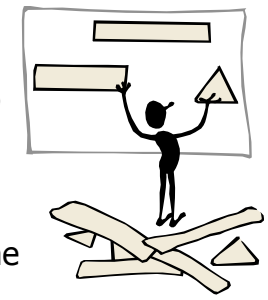
Elements of the HACCP Plan Validation Process

A. Product Description

1. All individual products are identified by brand name and/or common name in the HACCP plan. (Like products are grouped in an acceptable manner.)
2. Characteristics of the product(s) which are important to ensure it's safety are listed e.g., pH and a_w. The characteristics must be similar for all products covered by the HACCP plan(s).

   These characteristics are critical in controlling any common food safety concerns. Products with different characteristics cannot be grouped. For example, reduced oxygen packaged foods cannot be grouped under the same HACCP plan as sushi because the product characteristics are different.
3. Description of how the product is to be used, eg., raw, ready to eat, ready to cook, etc.
4. Packaging material and packaging conditions used for the product(s) are identified.
5. Anticipated shelf life of the product(s) listed under normal marketing conditions at given temperatures.

   If the determined shelf life of the product exceeds industry practices, laboratory data or scientific studies, the establishment must provide sufficient background data to support the safety of the chosen shelf life. In this case, any reference documents must be made available at the time of review.
6. Safe handling and usage information pertinent to the product is indicated, e.g., "keep refrigerated," best "use by" date, etc.
7. If applicable, the HACCP plan includes a description of any special controls required during shipping and storage, i.e. temperature requirements.
8. Labeling information for each product is available. The sample label is found to be consistent with: "Product Name", "Intended Use", "Safe Labeling Instructions" and "Special Distribution Control" on the HACCP plan.



10. When applicable, recipes are available upon request to determine if the formulation/method of preparation is consistent with those submitted with the HACCP plan.
11. When applicable, a floor plan, showing the layout of the preparation area.
12. When applicable, a brief description of the lot identification system.

B. Incoming Materials

1. All ingredients, incoming materials and processing aids coming in contact with the product(s) or used in the preparation of the product(s) are listed.

2. Hazard analysis is one of the most important steps in developing a HACCP plan. A wrong or faulty hazard analysis will significantly jeopardize the effectiveness of the HACCP plan.

   The establishment should evaluate hazards of significance and preventative measures needed for each food product and process. All hazards associated with incoming materials and ingredients should be specifically identified as biological, chemical, or physical in the HACCP plan. The hazards must at least include those that are commonly associated with a specific product.

   It may be necessary to use a variety of sources to gather information. Some of those sources could include scientific literature, regulations and other regulatory guidelines, laboratory records, and product specifications.

C. Process Flow Chart and Facility Layout Diagram

The HACCP plan includes a complete step-by-step flow diagram of the process and layout of the facility, indicating all pertinent processing steps, including where ingredients, packaging materials, etc. enter the flow and any preparation and storage designs that will impact the food flow or processing parameters.

Any hazards associated with possible cross-contamination are to be identified. It should also include product flow and employee traffic patterns within the establishment for products covered by the HACCP plan. The location of hand wash facilities should also be noted.

D. Critical Control Point Identification

The proper identification of Critical Control Points (CCPs) is crucial to the ultimate effectiveness of a HACCP plan. The plan must specify where each identified hazard will be controlled.

Hazards that cannot be controlled by the operator must be identified on the HACCP plan. The plan must indicate how these hazards will be addressed outside the establishment (i.e. purchasing pre-frozen fish, where the supplier is responsible for the freezing requirements as specified by regulation).

Note: The evaluation for completeness of the written CCPs will ensure that all relevant information dealing with critical limits, monitoring, corrective actions, verification procedures and record keeping is specified for each identified hazard.

E. Critical Limits Established

Critical limits have to be established for all critical components associated with each hazard that is controlled by a CCP.

Critical Limits must meet or exceed relevant regulatory and program requirements. Some establishments set critical limits to exceed regulatory requirements. This is acceptable, but the establishment should be made aware that if these limits are the ones written into the HACCP plan, the inspection will be conducted against these more stringent limits.

Critical limits normally include measurements such as temperature, time, moisture level, pH, a_w, available chlorine, and sensory attributes. When applicable, compare the critical limits found the establishment HACCP plan to those considered standard industry practice.

For Critical Limits without regulatory or program requirements, the company must validate that the critical limits in its plant specific HACCP plan are appropriate. This could include product sampling and laboratory analysis and should be relevant to the hazard being addressed.

F. Monitoring Procedures

Monitoring procedures exist for each critical limit at each CCP to ensure that the CCP is under control.

Monitoring procedures must be complete (Who, What, When and How). When applicable, these procedures must meet regulatory/program requirements.

G. Corrective Action Procedures

Corrective action procedures exist for each CCP.

Corrective action procedures must be complete (Who, What, When and How). When applicable, these procedures must meet regulatory/program requirements.

Corrective action procedures must state the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

1. The cause of the deviation is identified and eliminated
2. The CCP will be under control after the corrective action is taken
3. Measures to prevent recurrences are established

4. No product that could put the public at risk as a result of the deviation reaches the consumer

If a deviation, not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment must:

1. Segregate and hold the affected product, until an assessment is made to determine the acceptability of the affected product prior to sale

2. Take action, when necessary, with respect to the affected product to ensure that no product that could put the public at risk as a result of the deviation reaches the consumer

3. Perform or obtain reassessment by an individual trained in accordance with HACCP Plan requirements, to determine whether the deviation or other unforeseen hazard should be incorporated in the HACCP Plan

All corrective actions shall be documented in records that are subject to verification, under record keeping procedures, during the field verification inspection.

H. Verification Procedures

Verification procedures exist for each CCP.

Verification procedures must be complete (Who, What, When and How). This may include review of operations & records, and analytical testing.

Verification procedures ensure that the CCP is valid and effective (i.e. critical limits, monitoring procedures, and corrective action procedures are appropriate to ensure food safety).
Examples of on-going verification activities include:

- Calibration of monitoring equipment
- Direct observations of monitoring activities and corrective actions
- Record Review

I. Record Keeping

The following should be identified in the written HACCP plan:

- Corrective actions
- Records (including name and location)
- Verification

The requirement to record events at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation.

> For example: a sous-vidé process or cook-chill operation for a large institution would require more record keeping than a limited menu cook-serve operation. The simplest effective record keeping system that lends itself well to integration within the existing operation is best.

Plan Review and Revalidation

The operator is required to review the HACCP plan on a yearly basis to verify that it is effective over time. Whenever significant changes are made in any of the following areas, they must be incorporated into the HACCP plan the HACCP plan must be revalidated.

- Products added
- Formulations changed
- Processes or packaging added or changed
- Menu items added
- Suppliers, customers, equipment, or facilities changed
- Regulatory requirements changed
- Introduction of new technologies that may impact food safety

Review procedures must be written and include:

a. What is reviewed
b. The specified frequency for the review
c. Person responsible for the review
d. Person responsible for making necessary changes to the HACCP plan

Records must be kept to show that reviews are performed as written and to identify changes made to the HACCP plan. These records must include:

a. A description of the changes
b. Where the changes are located in the HACCP system
c. The date changes took place
d. Person responsible for verifying and, if necessary, validating the changes

Revalidation of the HACCP plan includes a documented on-site review and verification of all flow diagrams and CCPs in the HACCP plan.

Employee Training

A brief description of the employee training program must be provided.

Records should include the training courses completed by each employee. The depth and breadth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the HACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as product cooking temperatures and cooling times.

The training plan should be specific to the establishment's operation.

The use of recipes or Standard Operating Procedures (SOPs) which include the critical limits of cooking times and temperatures, with a final cooking time and temperature measurement step, should be included.

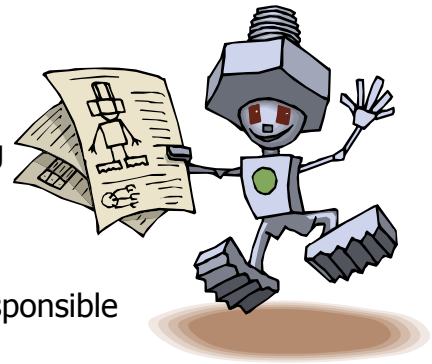
For all employees, the fundamental training goal should be to make them proficient in the specific tasks that the HACCP plan requires them to perform.

This includes the development of a level of competency in their decision-making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

Every time there is a change in a product or food operation within the establishment, the HACCP training needs should be evaluated.

For example, when a food establishment substitutes a frozen seafood product for a fresh one, proper thawing critical limits should be taught and then monitored for implementation. Training records should available, indicating names and dates of those in attendance.
NOTE: The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic day and signatures.

Validation of New/Modified HACCP Plans



Where an establishment has added a new process, requiring an additional HACCP plan, or modification of the existing one, the HACCP plan will require a full validation review.

The new/modified HACCP plan must be submitted to the responsible regulator in a timely manner.

As in the case of the initial validation process, the new/modified HACCP plan must be in operation prior to the verification audit.

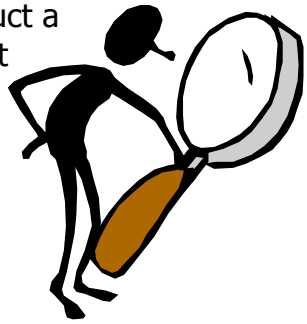
NOTE: The HACCP Plan Validation Checklist found in the Appendices is a tool that can be used by regulators when validating an establishment's HACCP plan.

The Verification Process

On-going field verification of the HACCP plan is conducted by the regulatory authority. Verification is necessary to ensure that the validated HACCP plan reflects current establishment conditions and that it is functioning effectively. The written HACCP plan must be validated and accepted as complete before the field verification inspection takes place.

The model *HACCP Field Verification Report Form* can be used by the regulatory agency, in conjunction with the inspection report form, to facilitate the verification process. The form can be easily completed by the regulator while validating the plan (see Appendix B).

In addition, the HACCP plan must be in operation prior to the verification inspection. In some cases, the regulatory authority may feel it necessary to conduct a pre-operational inspection to verify physical facilities and equipment requirements.



Such verification activities may include:

a. Review of the HACCP plan
b. Record review
c. Review of corrective actions and their resolution
d. Review of critical limits to ensure adequacy for controlling hazards
e. Direct observation or measurement at a CCP
f. Sample collection and analysis to determine the product meets all safety standards
g. On-site observations of activities carried out by the responsible employees
h. Review of modifications of the HACCP plan

Verification of the validated HACCP plan will be made for each CCP. This assessment is made after record review and on-site observations have been completed. The HACCP plan should not be accepted as final until the field inspector is confident that all requirements of the validated HACCP plan have been fulfilled. Failure to comply with the approved procedures must be documented on the inspection report form (FC 8-103.12 Conformance with Approved Procedures).

When any section of the validated HACCP plan does not comply with findings noted during the field inspection, the deficiencies should be noted on the *HACCP Field Verification Report Form* as well as on the inspection report form cover sheet. Deficiencies should also be described on the narrative section of the food establishment inspection report form, which serves as an order for correction (i.e. regulations, laboratory results, scientific data, etc.)

An emergency suspension of operations may need to be considered by the regulatory authority if significant non-compliance with monitoring of critical control points is noted.

When the regulator is satisfied that all deficiencies have been corrected, or that the components of the validated plan match findings noted during the field inspection, the HACCP plan approval process is complete. The *HACCP Field Verification Report Form* should be dated and signed by the reviewer for the record. An inspection frequency should then be established.

Elements of the HACCP Plan Verification Procedures

1. **Record Keeping Procedures**

The first step in the verification process is to review the records. This is usually done in the office. The approved HACCP Plan and associated records must be on file at the food establishment and available for review.

Records must be kept to show that CCPs are properly controlled. The establishment's HACCP plan must specify which records are in place for monitoring, corrective action, and verification procedures for each CCP.

Records documenting the monitoring of CCPs and their critical limits could include the recording of actual times, temperatures, or other quantifiable values, as described in the establishment's HACCP plan; the calibration of monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; and product code(s), product name or identity. Each of these records shall include the date the record was made.

Monitoring records should be retained at the establishment for a minimum of one year or, for the extent of the shelf life of the product, if it exceeds one year, and are available upon request.

Generally, the following are examples of documents that can be included in the total HACCP system:

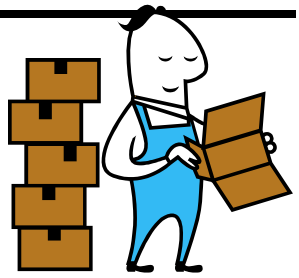
A. List of the HACCP team members and assigned responsibilities

B. Description of the product and its intended use

1. *Ingredients*

   Supplier certification and letters of guarantee documenting compliance with establishment and regulatory requirements.

2. *Preparation*
   Records from all monitored CCPs.



3. *Packaging*

   Records indicating compliance with specifications of packaging materials and sealing specifications.

4. *Finished product*

   a. Sufficient data and records to establish the efficacy of barriers in maintaining product safety.
   b. Sufficient data and records establishing the safe shelf-life of the product; if age of product can affect safety.
   c. Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

5. *Storage and distribution*

   a. Temperature records.
   b. Records showing no product shipped after shelf life date on temperature-sensitive products.

C. Flow chart indicating CCPs

D. Hazards associated with each CCP and preventive measures

E. Critical limits and preventive measures

F. Monitoring records

All monitoring activities are recorded and signed by the person doing the monitoring on a timely basis. They are up-to-date and complete for each CCP. Records show that the monitoring procedures are carried out as described in the validated HACCP plan and that they are effective.

G. Corrective action plans for deviations from critical limits

Validation records and modification to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

All deviations and the resulting corrective actions are recorded and initialed by the responsible person on a timely basis. They are up-to-date and complete for each CCP. Records show that the corrective action procedures are carried out as described in the validated HACCP plan and that they are effective.

H. Verification procedures

All verification activities are recorded and signed by the responsible person on a timely basis. They are up-to-date and complete for each CCP. Records show that the verification procedures are carried out as described in the validated HACCP plan and that they are effective.

I. Employee training

Records indicating that food employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures. These records should indicate the training courses completed by each employee.

2. Flow Chart and Facility Layout Diagram

On-site verification is performed to confirm that the flow chart is accurate in relation to hazard identification and conforms to all aspects of the validated HACCP plan. The facility layout diagram must also be accurate and complete in relation to hazards associated with cross-contamination from product flow and employee traffic patterns.

3. Recipes/Formulations/Method of Preparation

Assessment is made for completeness of the product description and to ensure that the establishment is following its written procedure. When possible, this review should take place while the product is being prepared.

Obtain the recipe/formulation/method of preparation that corresponds to the validated HACCP plan.

If a deviation is found, stop and ask the company to review all its formulation/methods of preparation for this HACCP plan.

4. Incoming Materials

Compare actual ingredients and incoming materials to the establishment's HACCP plan. This will include raw materials, product ingredients, processing aids, and packaging materials.

5. Labels

Randomly select one or more labels covered by the HACCP plan. Inspect the label(s) to ensure it matches the written product description.

If a deviation is found, select at least one more label. If an additional deviation is found, stop and ask the company to review all its labels for this HACCP plan.

6. Monitoring Procedures

Monitoring procedures must be defined for each critical limit at each CCP to make sure the CCP is under control. Individuals are interviewed and should be able to demonstrate that they have an understanding of the critical limits, reason & importance of the monitoring of this CCP and how to perform the related monitoring procedures, including record keeping.

Monitoring procedures are to be ongoing at all times during processing and must be done in a location that accurately reflects the critical limit. In some cases, the frequency of monitoring reflects regulatory requirements (e.g., visual examination of packaging for proper vacuum seal).

Results of monitoring procedures must be readily available and give information on a timely basis allowing a decision to be made on the acceptability of the product and conformance to the validated HACCP plan.

7. Corrective Actions

A deviation occurs when a predetermined critical limit is exceeded, resulting in a potential impact on the health & safety of the product. In some cases, the corrective action procedures reflect regulatory requirements (e.g., proper temperature control, sufficient acidification, etc.). Corrective actions must include the course of action to be taken in order to deal with the deviations when they occur and they must match corrective action procedures listed in the validated HACCP plan.

Individuals are interviewed and should be able to demonstrate that they can identify deviations and understand the required corrective action to be taken as specified in the validated HACCP plan.

8. Verification Procedures

Verification procedures include the review of operations and records. They could also include analytical testing to determine if the CCP is valid and effective (e.g., the review of the corrective action records by the responsible person at a set frequency to determine if appropriate corrective action was taken when a deviation occurred). They are not intended to make a decision on the acceptability of the product. When applicable, compare actual verification procedures to those noted on the validated HACCP plan.

Individuals are interviewed and should be able to demonstrate that they understand how to perform the verification procedures and can complete the required records.

9. Record Maintenance

It is the operator's responsibility to establish a system for maintaining records. The HACCP Plan must be dated in order to identify the most current version. In addition, all *modified* pages of the HACCP plan must be signed by the HACCP coordinator or designated person to indicate management approval.

Copies of the dated and signed pages must be distributed to all users as required.

Only the most current version of a HACCP plan should be in use. All obsolete documents/pages should be removed.

Non-compliant HACCP Systems

A HACCP system may be found inadequate if, during the field verification inspection, the regulator finds that actual procedures, corrective actions, records, critical limits, or verification procedures are not in compliance with regulations or the validated HACCP Plan. Some of these inadequacies may include:

- The HACCP Plan in operation does not meet the requirements as stated in the validated HACCP Plan
- Establishment personnel are not performing tasks specified in the validate HACCP Plan
- The establishment fail to take corrective actions, as required by regulation, or as stated in the validated HACCP Plan
- HACCP records are not being maintained as required by regulation or as stated in the validated HACCP Plan
- Adulterated product is being produced or transported

Regulation: 8-103.12 Conformance with Approved Procedures

If the regulatory authority grants a variance as specified in § 8-103.10, or a HACCP plan is otherwise required as specified under § 8-201.13, the permit holder shall:

(C) Comply with the HACCP plans and procedures that are submitted as specified under § 8-201.14 and approved as a basis for the modification or waiver; and

(D) Maintain and provide to the regulatory authority, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring critical control points,
(2) Monitoring of the critical control points,
(3) Verification of the effectiveness of an operation or process, and
(4) Necessary corrective actions if there is failure at a critical control point

Enforcement/Corrective Actions

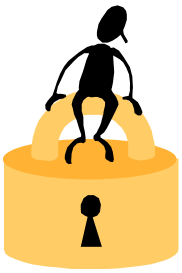
During the field verification inspection, any finding, considered to have an immediate impact on public health and safety, must be assessed. When necessary, immediate corrective, or compliance action, must be taken to control the hazard and/or the product.

On-site corrective actions, or subsequent enforcement actions, should be appropriate to the type of violation and could include one or more of the following:

- Accelerated cooling of foods when cooling time limits can still be met
- Reheating when small deviations from hot holding have occurred
- Continued cooking when proper cooking temperatures have not been met
- Initiated use of gloves/tongs/utensils to prevent hand contact with ready-to-eat foods, or required hand washing when potential contamination was observed.
- Required hand washing when potential contamination is observed
- Restriction/Exclusions
- Modifications to the HACCP Plan
- Disposal of foods that have experienced extreme temperature abuse or do not comply with critical aspects of the HACCP Plan
- Embargo or disposal of foods from unapproved sources

Enforcement/Corrective Actions Cont'd.

- Warning letters
- Re-inspection
- Citations/Administrative fines
- Permit suspension
- Hearings
- Suspension
- Emergency closure



Follow-up Field Verification Inspections

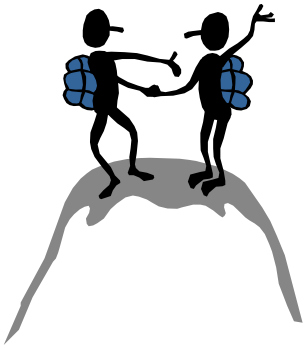
It is recommended that follow-up verification inspections be conducted:

- Routinely or on an unannounced basis, to ensure that selected CCPs are under control
- When established criteria have not been met
- Patterns of non-compliance\non-conformance noted, indicating a systematic failure of management control
- When foods prepared at the establishment have been implicated as a vehicle of foodborne disease
- To verify that changes have been implemented correctly after a HACCP plan has been modified
- When requested on a consultative basis and resources allow accommodating the request

Review of changes to the initial HACCP plan should be carried out during a follow-up regulatory inspection. The establishment's records will form the basis to validate and verify the HACCP plan changes.

Prior to the follow-up inspection, the regulator may wish to contact a regional expert for clarification or direction with regard to HACCP plan changes.

Following a successful inspection for changes to the HACCP Plan, the regulator should issue an acceptance letter to the establishment.



Appendices

A HACCP Plan Review Application
B HACCP Field Verification Report Form

Appendix A HACCP Plan Review Application

Hazard Analysis Critical Control Point (HACCP) Plan Review Application

Establishment Name:	**Tel:**
Address:	**Fax:**
Owner/Person-in-Charge:	**E-mail:**
HACCP Plan Contact:	**Tel:**

Please note that <u>pre-requisites</u> for plan approval are 1) compliance with 105 CMR 590.000 and 2) the implementation of effective standard operating procedures (SOPs) for:

Food Protection Management	Approved Food Sources
Employee Health and Hygiene	Protection From Contamination
Time/Temperature Controls	Protection From Chemicals
Cleaning and Sanitizing	Facilities/Equip. Design & Maint.

Please review/use this checklist to verify that you have included the following in your plan:

- ❑ Purpose of Submission (i.e. Variance or Code Requirement - Include Code Reference)
- ❑ Name of food product and process for which the plan is being submitted.
  - Include formulation of ingredients, if required.
  - Include facility layout, if required.
  - Include copy of labeling, if required.
- ❑ A flow chart, showing how the product flows through the establishment, including an accurate description of how the food is prepared, held, served, transported etc.
- ❑ Identification of each Critical Control Point (CCP) in the process.

For <u>Each</u> CCP…….

- ❑ A description of the hazard(s)
- ❑ A description of monitoring procedure(s) and a sample of form(s) that will be used to document the monitoring activities.
- ❑ A description of corrective action(s) and sample of form(s) that will be used to document the corrective action(s).

- ❑ A description of verification procedure(s) and sample of form(s) that will be used to document verification activities by PIC.
- ❑ A description of plan verification and validation procedures (Ex. Annual review, scientific data, modifications to plan.) Please include:
  - A statement that an updated, signed copy of the plan will be maintained on the premises for review by the regulatory authority.
  - Name of person responsible for administering and updating plan.
  - A statement that the regulatory authority will be informed of any significant changes in the process that may affect the accuracy or effectiveness of the plan prior to implementation, and
  - A statement that updated plans will be submitted to the regulatory authority, upon request.
  - Laboratory data, if required.
- ❑ Employee training plan and sample form(s) that will be used to document employee training.

All of the information submitted is accurate to the best of my knowledge. All violations noted during previous food safety inspections have been corrected and the operation is in compliance with 105 CMR 590.000 Minimum Sanitation Standards for Food Establishments – Chapter X.

I understand that failure to comply with this plan and/or falsification of monitoring, corrective action, or verification records may result in a suspension of operations in accordance with 105 CMR 590.010 (FC 8-103.12).

_____

Permit Holder or Person-in-Charge Signature/Title Date

For Board of Health Use:

Date	Reviewer	Comments	Accepted

Implementation Date: _____

Appendix B HACCP Field Verification Report Form

HACCP Field Verification Report Form

Establishment Name	
Address	
Person-in-Charge	
Date Written Plan Validated	
Food Product and Process	

Validated Plan	**In**	**Out**
HACCP plan validated by the regulatory authority/available for review		

Prerequisites	**In**	**Out**
Establishment has implemented effective standard operating procedures and is in compliance with 105 CMR 590.000. (Document violations on Food Establishment Inspection Report Form)		

Accurate Description of Product/Process and Intended Use	**In**	**Out**
Food flow is consistent with flow chart (Attached)		

Hazard(s)	**Critical Control Point(s)**	**Preventive Measure(s) / Critical Limit(s)**

Monitoring Procedures	**In**	**Out**

Food Employee Knowledge of Corrective Actions if Critical Limit(s) Exceeded or Not Met for each CCP.	**In**	**Out**
Verification Process	**In**	**Out**
Records available and accurate to address Critical Limits at each CCP. (Sample Logs Attached, i.e. Monitoring, Corrective Actions)	**In**	**Out**
Employee Training	**In**	**Out**
Evidence of food employee training provided.		
Inspector:		
Date of Field Verification:		

Corrective Action Taken?

- ❑ **NO** (Establishment is in compliance with approved procedures)
- ❑ **YES** (If Yes, please indicate corrective action taken below.)

  - ❑ Order for Correction Issued (Inspection Report Form or Letter)
  - ❑ Emergency Suspension of Operation
  - ❑ Embargo
  - ❑ Voluntary Disposal
  - ❑ Employee Restriction/Exclusion
  - ❑ Employee Training
  - ❑ Other:_____

References

Association of Food and Drug Officials, 1998. Retail Meat and Poultry Processing Guidelines. York, PA.

Codified MA Regulation 105 CMR 590.000 *Minimum Sanitation Standards for Food Establishments State Sanitary Code, Chapter X*

Cutter, C.N. 2000. *Proper Processing of Wild Game and Fish*. Penn State Cooperative Extension, University Park, PA

Fish and Fishery Products Hazards and Controls Guide, Second Edition, January, 1998 and June, 2001.

Food and Drug Administration, FDA 1999 Food Code

FDA Managing Food Safety: A HACCP Principles Guide for Operators of Food Establishments at the Retail Level January 2002

FDA Managing Food Safety: A Regulator's Guide for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections April 2002

FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers 1999

FDA's Recommended National Food Regulatory Program Standards, June 2001

Florida Cooperative Extension Service / Institute of Food and Agricultural Sciences / University of Florida. Document CIR 1179: *A Model HACCP Plan for Small-Scale, Fresh-Squeezed (Not Pasteurized) Citrus Juice Operations*. Published: March, 1997, R.H. Schmidt, C.A. Sims, M.E. Parish, S. Pao, and M.A. Ismail.

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), *Hazard Analysis Critical Control Point System: Concept and Application* (Geneva, June 1995).

Mead, P.S., Slutsker, L., Dietz, V., McCaig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., Tauxe, R.V., 1999. Food-related illness and death in the Unites States. Emerging Infectious Diseases Vol. 5, No. 5, pp. 38.

National Advisory Committee for the Microbiological Criteria for Foods (NACMCF). 1997 Hazard Analysis and Critical Control Point System, USDA – FSIS Information Office. 1997.

National Advisory Committee for the Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point System*, adopted March 20, 1992.

National Shellfish Sanitation Program Guidelines for Control of Molluscan Shellfish, 1999 Revision

"Overview of Biological, Chemical, and Physical Hazards" in "HACCP Principles and Applications", Merle Pierson and Donald A. Corlett, Jr. (Eds.), 1992 p 8-28. Chapman and Hall, New York.

Retail Meat and Poultry Processing Training Satellite Conference Series. Cosponsored by: AFDO and FSIS.

Additional Resources

AFDO Meat and Polultry Processing at Retail - Training Manual.
Produced by AFDO, the University of Florida and USDA/FSIS. 2002 http:www.afdo.org

FDA Food Code, current edition, may be purchased from the U.S. Department of Commerce, National Technical Information Service, via telephone: (703) 487-4650 or electronically via the FDA website:
http://www.cfsan.fda.gov/~ear/retail.html

Fish and Fishery Products - Code of Federal Regulations, Title 21, Part 123 Fish and Fishery Products.

Fish and Fishery Products Hazards and Controls Guide, Third Edition, June 2001. Food and Drug Administration, Washington, D.C. May be purchased from: National Technical Information Service
U.S. Department of Commerce, (703)-487-4650 or electronically at
http://www.cfsan.fda.gov/~comm/haccpsea.html

National Shellfish Sanitation Program Model Ordinance for Molluscan Shellfish, available on the FDA/CFSAN website at:
http://www.cfsan.fda.gov/~ear/nsspotoc.html or may be purchased from National Technical Information Service, U.S. Department of Commerce, (703)-487-4650.

Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors, available on the FDA/CFSAN website at:
http://www.cfsan.fda.gov/~dms/retrsk.html